Exhibit 16

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to the Declaration of Nicholas N. Paul in Support of
Plaintiffs' Opposition to Defendants' Joint Motion for Partial Summary Judgment

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL DOCKET NO. 1456 Master File No. 01-12257-PBS (Original Central Dist. of California No. 03-CV-2238)
THIS DOCUMENT RELATES TO: State of California ex rel. Ven-A-Care v. Abbott Laboratories, et al. 03-CV-11226-PBS	)	Judge Patti B. Saris

EXPERT REPORT OF

STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

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I. QUALIFICATIONS AND BACKGROUND

1. I make this statement as an independent expert in pharmacy, pharmaceutical economics, and public policy. I hold the following positions and titles in the College of Pharmacy at the University of Minnesota: Head, Department of Pharmaceutical Care & Health Systems; Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics; Professor of Pharmaceutical Management and Economics; and Director of the PRIME Institute. I hold a Bachelor of Science in Pharmacy (1974, University of Missouri-Kansas City), a Doctor of Pharmacy and Residency Certificate (1977, University of Kentucky), a Master of Arts in Public Administration (1979, Ohio State University) and a Doctor of Philosophy in Administrative and Social Sciences in Pharmacy (1984, Ohio State University). A list of my professional memberships, professional activities, research activities, publications and other scholarly activities, citation of work in public media, offices held in professional and scientific organizations, university administrative and service positions, honors and awards, and civic and community activities is contained in a copy of my most recent curriculum vitae, which is attached hereto as Exhibit "1."

2. My experience related to pharmaceutical economics and public policy research spans more than 30 years. I am currently the director of the PRIME Institute at the University of Minnesota, which was established in 1991 to conduct research related to the management and economics of the pharmaceutical marketplace. Prior to accepting a position at the University of Minnesota, I directed the Pharmaceutical Economics Research Center (PERC) at Purdue University from the time the Center was established

in 1986 to 1991. PERC also engaged in research related to the economics of the pharmaceutical marketplace.

3. I was appointed by the United States Congress to the Prescription Drug Payment Review Commission, an 11-member independent Congressional commission that served as an advisory body to the U.S. Congress with respect to the outpatient drug program established by the Medicare Catastrophic Coverage Act of 1988.

4. I provided professional staff analysis for the Kentucky Drug Formulary Council, Department for Human Resources, Commonwealth of Kentucky from 1975 to 1977. The Kentucky Drug Formulary Council was the nation's first governmental body to establish a generic equivalence standard for determining whether or not brand and generic drug products could be considered as generic equivalents and, therefore, could be substituted for one another. This generic equivalence formulary preceded the FDA's Orange Book.

5. As an academic researcher, my principal areas of interest have included trends in the pharmaceutical marketplace at all levels, the structure and performance of pharmaceutical markets, competition between and among brand name and generic drugs, and the impact of generic competition, including generic entry into brand drug markets. I have also conducted research on medication use and expenditures by the elderly, drug coverage under health insurance plans, access and affordability of pharmaceutical products, in addition to pharmacoeconomic research and policy analysis related to all aspects of the pharmaceutical marketplace. I have performed pharmacoeconomic research for many organizations, including, among others, the U.S. Centers for Medicare and Medicaid Services (CMS)—formerly known as the Health Care Financing Administration (HCFA), the U.S. Government Accountability Office (GAO)—formerly

known as the General Accounting Office (GAO), the U.S. Food & Drug Administration (FDA), the U.S. Congress's Office of Technology Assessment (OTA), pharmaceutical firms, professional societies, and various state governments and agencies. I have also led pharmaceutical research and policy projects at the international level for governments including Thailand, Singapore, Spain, Canada, Argentina, Venezuela, South Africa, South Korea, and Taiwan.

6. Based upon on my experience in professional consulting and academic research, I have particular expertise in economic and public policy issues in the pharmaceutical marketplace. One of the major focuses of my research and work relates to the impact and role of generic drugs and generic competition. In this context, I am well versed in assessing the economic impact of generic competition on all levels of the pharmaceutical marketplace, including on the various channels of distribution and upon consumers, the behavior of brand manufacturers faced with generic competition, and the mechanisms by which generic competition is fostered and, by contrast, impeded. Another of the major focuses of my research and work relates to the reimbursement for prescription drugs under private and public insurance programs including Medicaid and Medicare. In this context, I am well versed in assessing the economic impact of reimbursement policies on all levels of the pharmaceutical market including providers, patients, and payers.

7. My research projects directly related to general issues in the pharmaceutical market, such as drug prices, competition, generic entry, pricing, market penetration, channels of distribution, the effects of generic competition on the market for originator drug products, and other economic and marketing issues, also are listed in my curriculum vitae (see Exhibit "1").

8. My experience includes conduct of several studies specifically for the Centers for Medicare and Medicaid Services (CMS)—the federal agency that oversees both Medicare and Medicaid. Among the studies conducted for CMS or its predecessor agency (HCFA, the Health Care Financing Administration) are the following:

a. *Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare* (Department of Health and Human Services, June 27, 1989, Stephen W. Schondelmeyer and Joseph Thomas);

b. *Impact of the Medicaid Drug Rebate Program on Expenditures, Utilization, and Access: Final Report* (Health Care Financing Administration, Contract # 500-92-0022, DO #3, April 1995, Stephen W. Schondelmeyer, Judy A. Johnson, Dong Churl Suh, George Wright, Ann Cherlow, Andrew Asher, Angela Schmitt, Portia DeFilippes, Jon B. Christianson, John Kralewski).

c. *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, Stephen W. Schondelmeyer and Marion V. Wrobel);

d. *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle)

e. *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-

049, Task Order 1, September 26, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper), and

f. *Evaluation of Pharmaceutical Pricing Under Medicare Drug Card: Final Report* (U.S. Dept. of Health & Human Services, Assistant Secretary for Planning and Evaluation, Task Order Contract #100-03-0106, November 16, 2006, Stephen W. Schondelmeyer, Margaret Artz, Shriram Parashuram, Lois Olinger, and Sarah Shoemaker).

9. A list of other cases in which I have testified as an expert at trial or by deposition is attached as Appendix B to my curriculum vitae (see Exhibit "1").

10. I am being compensated for my time spent working on this case at the rate of $600.00 per hour for time spent testifying, or preparing for testimony, and $400.00 per hour for all other time.

II. SCOPE OF REPORT

11. I understand that this action was originally initiated by the plaintiff, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"). I further understand that the State of California has intervened as to certain defendants. The suit at the time of this report names Dey, Inc., and Dey L.P. (collectively known as "Dey"); Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc. (collectively known as "Mylan"); and Sandoz, Inc. (referred to as "Sandoz"). Collectively, Dey, Mylan, and Sandoz will be known as the "Defendants."

12. I have reviewed California's First Amended Complaint (California's First Amended Complaint) in Intervention filed against Dey, Mylan, and Sandoz. The Plaintiffs allege, among other things, that "Defendants defrauded the Medicaid program

of the STATE OF CALIFORNIA (known as "Medi-Cal") by reporting excessively high and false prices for some of their prescription drugs with knowledge that Medi-Cal used these reported prices for establishing reimbursement to its Medi-Cal providers for these drugs. As a result, Medi-Cal sustained significant losses to its program by making reimbursement payments for the drugs at illegally excessive prices compared to the prices at which the Medi-Cal providers actually acquired the same drugs." [*See* California's First Amended Complaint, ¶ 1].

13. I have reviewed documentation, including some of Defendants' business records provided as discovery responses in this case, certain documents and records of the state and federal Medicaid programs, certain documents of the Medi-Cal program, various deposition testimony and exhibits, literature in the field of pharmaceutical economics, and other publicly available documents and sources. In addition to those sources specifically referred to in this Report, all materials I considered in formulating my opinions are being produced or identified with this report.

14. I have been asked to testify about the following subject matters: an overview of the pharmaceutical market; an overview of pharmaceutical pricing; a description of the federal-state Medicaid drug programs including Medi-Cal; a description of the Medicaid drug rebate program; a review of Dey's, Mylan's, and Sandoz' price reporting to the Medi-Cal program and to commercial price databases; and other topics related to pharmaceutical pricing and reimbursement. Specifically, I have been asked to render an opinion as to the processes of Medicaid and Medi-Cal programs with respect to drug reimbursement and the role of drug manufacturers, including Dey, Mylan, and Sandoz, as price reporters in the Medicaid and Medi-Cal pharmaceutical payment systems.

15. My opinions contained herein are based upon my review of the above-described documents, as well as upon my qualifications and 30 years of experience described above. I understand that discovery is ongoing in this case, and as always with an expert report, I reserve the right to amend and update my opinions based upon additional information that may be provided to me, including additional discovery, or that may become known to me by other appropriate means in the future.

III. SUMMARY OF FINDINGS

16. This case involves Dey, Mylan, and Sandoz and the prices they reported to the commercial databases and sometimes to federal and state Medicaid programs including Medi-Cal. The time period covered for this case encompasses from January 1, 1994, and continuing through December 31, 2004. [*See* California's First Amended Complaint, ¶ 43.] The general substance of my opinions is briefly summarized here. The remainder of the report provides more detailed opinions and the bases for my opinions.

17. The bases for my opinions are the documents and testimony I have reviewed in this and related litigation, my education and experience as reflected in my curriculum vitae (Exhibit 1) and my accumulated knowledge and understanding of the pharmaceutical industry, pharmacoeconomics, government health care policy, pharmaceutical reimbursement policies and practices, and other related areas.

18. The federal and state Medicaid programs, during the operative time frame, used pricing information reported by drug manufacturers, including Dey, Mylan, and Sandoz to calculate the estimated acquisition cost (EAC) and other reimbursement amounts for a drug product as a means to pay providers for the ingredient cost of each prescription.

19. The prices reported by drug manufacturers, including Dey, Mylan, and Sandoz to the commercial drug price databases were used by all, or virtually all, state Medicaid programs as a basis for the formulaic calculation of the reimbursement amount for prescriptions provided to Medicaid recipients by pharmacies and providers. Specifically, the Medi-Cal program uses the price information from manufacturers and the commercial price database in a formula to determine, among other things, the cost of the drug product which is the lowest of: "the Estimated Acquisition Cost (EAC), the Federal Allowable Cost (FAC) [also known as the Federal Upper Limit (FUL)], or the [state] Maximum Allowable Ingredient Costs (MAIC)/Maximum Allowable Product Cost (MAPC) for the Standard Package size… The price charged to the program shall not exceed that charged to the general public." [Cal. Code Regs. tit. 22 §51513(a)(11), effective 3-1-95; see also Cal. Code Regs. tit. 22 §51513(b)(1)(A), effective 3-1-95].

20. Drug manufacturers, including Dey, Mylan, and Sandoz were aware that the state Medicaid programs, and specifically Medi-Cal, based their estimated acquisition cost (also known as the drug product ingredient cost) reimbursements on manufacturers' reports of drug product prices to the commercial price databases (i.e., First DataBank in the case of Medi-Cal). Drug manufacturers, including Dey, Mylan, and Sandoz were aware that the Medi-Cal program intended to use the manufacturer reported prices (i.e., AWP) to commercial price databases (i.e., First DataBank in the case of Medi-Cal) as the basis for "the Department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." [Cal. Code Regs. tit. 22 §51513(a)(6), effective 3-1-95].

21. The general intent of the federal and state Medicaid programs was published in a Health Care Financing Administration (HCFA) memo to State Medicaid Directors as far back as 1977 as early as 1987 in federal regulations [42 CFR Part 447.301; see also Fed Reg, Vol. 52, No. 147, July 31, 1987, pp. 28648-58], and this intent has been routinely referenced in the annual volumes of the National Pharmaceutical Council's publication "Pharmaceutical Benefits Under State Medical Assistance Programs" (also referred to as the "NPC Medicaid Book"), and other places. Sandoz directly and later through Novartis, has been a member of the National Pharmaceutical Council throughout the entire period at issue in this case. Dey was also aware of, and referenced, the National Pharmaceutical Council publications on Medicaid program reimbursement in internal documents and communications as far back as 1995. [Memo from Dey Laboratories to Beth Raider, Price Alert and Pharmacy Blue Book Update, May 30, 1995, attachment "Medicaid Rx Reimbursement Report, Drug Topics, February 6, 1995, Source: National Pharmaceutical Council]. The size and importance of the Medicaid program is so great that any key person in an area such as marketing, pricing and reimbursement, product management, or business strategy at a pharmaceutical company would have to be aware of the payment policies of Medicaid, or at least of where to find information on such policies. Key personnel at major pharmaceutical companies, including Dey, Mylan and Sandoz, would have been aware of the Medicaid payment policies, NPC Medicaid Book, and most probably had a copy of the NPC book in their offices.

22. The federal regulations regarding payment for prescription drugs under Medicaid were amended in 1987 to include the definition which states that "estimated acquisition cost means the agency's best estimate of the price generally and currently paid by

providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." [42 CFR Part 447.301; see also Fed Reg, Vol. 52, No. 147, July 31, 1987, pp. 28648-58]. Throughout the relevant time period and indeed up until the time of this report (June 2009) the regulation defining estimated acquisition cost remained in effect.

23. Drug product prices had been routinely reported by manufacturers to the drug price compendia, such as Blue Book (First DataBank), MediSpan, and Red Book during the time frame of this complaint. Brand name prescription drugs accounted for 80% to 90% of Medicaid program expenditures from 2004 back to 1994 at the beginning of the time period for this case. The prices of drug products, and especially brands, reported by drug manufacturers to drug price compendia traditionally had a predictable relationship to actual market prices generally and currently paid by pharmacies in the marketplace, except for instances where a manufacturer for its own reasons chose to report prices with inflated relationships when compared to the actual prices that were generally and currently paid by pharmacies in the marketplace. This behavior of certain drug manufacturers, especially generics, has resulted in reported prices (i.e., AWP) that have become inflated progressively over time. In addition, the AWPs, especially for generics, have become increasingly arbitrary and have an unreliable relationship to actual prices generally and currently paid by providers.

24. Policymakers and both Medicaid and Medi-Cal program administrators were generally unaware of the conduct of certain drug manufacturers whereby reported prices (i.e., AWP) were inflated well beyond the actual prices in order to engineer an inflated price spread and to result in inflated reimbursement, including Medi-Cal reimbursement.

Such practices were brought to the attention of certain government officials by Ven-A-Care and have been examined over time by various government agencies.

25. To the extent that Dey, Mylan, and Sandoz reported AWPs to the commercial drug price databases that were not predictably related to actual prices that Dey, Mylan, and Sandoz knew were generally and currently paid by customers, then Dey, Mylan, and Sandoz engaged in the conduct, described above, whereby some drug manufacturers have caused AWP and other price reports to become decreasingly representative of actual prices generally and currently paid by pharmacies in the marketplace. This pricing behavior has caused increases in Medi-Cal reimbursement amounts that were unintended by, and unknown to, the Medi-Cal drug programs.

26. As described later in this report, the reporting of inflated price information to the compendial sources (i.e., Blue Book, MediSpan, or Red Book), which Dey, Mylan, and Sandoz knew would result in an inflated AWP being published, also led to the inflation of Medi-Cal reimbursement amounts when compared to the actual prices at which the drug products were sold.

IV. OVERVIEW OF THE PHARMACEUTICAL MARKET

27. Prescription drugs are the most widely used method for treating medical and health-related conditions. In 1996, the total retail prescription sales[1] in the U.S. were reported to be about $72 billion and, by 2006, total retail prescription sales had grown to nearly $250 billion. The total number of outpatient prescriptions grew from 2.2 billion in

[1] Total retail sales as defined by IMS Health includes outpatient prescription sales of independent pharmacies, traditional chain pharmacies, supermarket pharmacies, mass merchandiser pharmacies, and mail order pharmacies. [IMS Health data as reported by the National Association of Chain Drug Stores on its website (http://www.nacds.org/wmspage.cfm?parm1=507), May 7, 2007].

1996 to 3.4 billion in 2006 and with adjustment for mail order prescriptions (that is, 3 months supply per prescription counted as 3 one-month prescriptions) was equal to about 3.9 billion monthly prescriptions. This prescription volume represents about 13 prescriptions per person per year in the United States in 2006.

28. The expenditure on prescription drugs is a substantial share of the total national health expenditures. Outpatient prescription drugs accounted for about 10.1% of national health expenditures in 2005. [U.S. Department of Health & Human Services (DHHS), Office of the Actuary, National Health Accounts, 2004. Note: The health spending projections were based on the 2004 version of the NHE released in January 2006 with data for years from 2005 to 2015 projected]. However, when prescription drug spending in all other sectors of the national health accounts (i.e., hospitals, physicians and clinics, long term care, home health, dentists, managed care, active military and military retirees, public health service, 340B facilities, the Veterans Administration and other settings) is taken into account, the expenditure on prescription drugs is approximately 17.5% of national health expenditures.

29. Since before 1990, outpatient prescription drug expenditures have been growing at a rapid rate. The annual growth rate in prescription drug spending has been in double digits for nearly all of the 15-year period from 1991 to 2006. Outpatient prescription drug spending in the 1990s, and the first part of the present decade, has grown considerably faster than health care spending overall. [U.S. DHHS, Office of the Actuary, National Health Accounts, 2004 version, released January 2006].

A. Channels of Distribution

30. In a broad sense, the structure of the pharmaceutical market can be described by two major features: (1) the channels of distribution for prescription drugs, or how the drug products flow through the market, and (2) the sources of payment for prescription drugs, or how the dollars flow through the market. These two structural perspectives are discussed in one of my reports for the Centers for Medicare & Medicaid Services. [Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, pp. 9-13].

31. First, regarding channels of distribution, there are three primary levels in the distribution channel: (1) manufacturer or marketer, (2) wholesaler, and (3) pharmacy or other provider. Each of these channels of distribution and its role in the market was described in my 2004 report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp.9-11]. The following sections are excerpted from that report:

> Channels of distribution for prescription drug products are the pathways that drug products follow from the pharmaceutical manufacturer to the patient who ultimately uses the medication. There are three primary levels in the distribution channel: (1) manufacturers, (2) wholesalers, and (3) providers. Manufacturers and marketers reported $215.7 billion in revenue from prescription drugs in 2002. The flows of these drug products through various channels of distribution are depicted in Exhibit 4. [*Attachment 2 in this report*].

32. The role of manufacturers and marketers in the pharmaceutical market was also described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 9-10] as follows:

> The manufacturer level is the starting point for prescription drugs as they begin their movement through the various channels of distribution. Any firm that manufactures or sells a prescription drug in the United States must hold a new drug application (NDA) or an abbreviated new drug application (ANDA) issued by the U.S. Food & Drug Administration (FDA). However, other firms may market a prescription drug without holding either an NDA or an ANDA, if such a firm has entered into a licensing agreement with an NDA or ANDA holder.
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> Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digits) for each drug product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.
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> Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. Not all NDC holders participate in the Medicaid Drug Rebate program. Approximately 544 pharmaceutical companies (or labelers) currently participate in the Medicaid Drug Rebate Program.

33. The role of wholesalers and distributors in the pharmaceutical market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 10-11] as follows:

> Manufacturers or marketers of prescription drugs most often sell their drug products to a middleman, or intermediate level, before the drug product reaches the pharmacy or physician that will provide the drug to the patient. National wholesalers are the primary intermediate level in the channel of distribution process accounting for 45.7 percent of prescription drugs ($98.5 billion) in 2002, (see Exhibit 4) [*Attachment 2 in this report*]. Other intermediate channels of distribution include chain warehouses with 32.3 percent ($69.8 billion) of the market, regional and specialty wholesalers with 9.3 percent ($20.2 billion) of the market, and group purchasing organizations that usually contract with a wholesaler to perform the distribution function on their behalf. About 12.6 percent of prescription sales by drug manufacturers are made directly to providers (e.g., physicians or hospitals) or pharmacies.
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> The principal trade organization representing wholesalers in the United States is the Healthcare Distribution Management Association (HDMA). In 2002, the HDMA reported that there were more than 72 distributor companies

operating approximately 242 distribution centers.[2] On average, these distribution centers handle more than 21,000 different healthcare items. More than one-half of the items distributed (about 11,000) are prescription pharmaceuticals and biologics, and the additional items include "over-the-counter and herbal products, health and beauty aids, medical and hospital supplies, durable medical equipment and home healthcare items."[3] The three largest wholesalers (Cardinal Health, AmeriSource Bergen, and McKesson) each have about 32 percent of the national market and collectively account for 97 percent of the drug sales that flow through national wholesalers and 83 percent of all wholesalers (national, regional, and specialty). Wholesalers add a markup and fees to the manufacturer's drug product cost to cover the cost of distribution and other services they provide. The total wholesaler gross margin averaged about 4.3 percent in 2002 with a range from 3.7 to 5.5 percent for the 25th and 75th percentile. These costs are added to the manufacturer's drug product cost and passed on to the pharmacy or provider purchasing through a wholesaler.

In addition to full-line national wholesalers, there are also regional and specialty wholesalers that handle just under 10 percent of manufacturer drug sales. Regional wholesalers are usually similar to the national full-line wholesalers, but they typically have only one or a few distribution centers limited to a relatively small geographic region. Specialty wholesalers, in contrast, may have a national market presence, but instead limit the types of drug products stocked to a very narrow set. Specialty wholesalers may focus on generic drugs, biological agents, or drugs for a specific therapeutic purpose such as oncology, dialysis, or HIV therapy. Specialty wholesalers may also focus on serving certain facility types such as long term care pharmacies, home health agencies, or hospice facilities.

Group purchasing organizations (GPOs) may act on behalf of a group of providers to negotiate price with drug manufacturers. Most group purchasing organizations, however, do not ever take possession of, or handle, the drug product. Instead, GPOs often will contract with a traditional wholesaler to perform the wholesaling and distribution function on behalf of the GPO and its members.

A number of large chain pharmacies have developed and operate their own distribution centers rather than purchasing drug products through traditional wholesalers. Chain warehouses accounted for 32.3 percent ($69.8 billion) of all prescription drug sales by drug manufacturers in 2002. Chains that operate their own warehouses incur expenses similar to those seen by traditional wholesalers (range from 3.7 to 5.5 percent). When a chain pharmacy performs the warehousing function in addition to the retail distribution and counseling functions, the chain does have additional costs similar to those that a wholesaler would have added to the manufacturer's drug product cost.

[2] Healthcare Distribution Management Association, *2002 HDMA Industry Profile and Healthcare Factbook*, 2002, p. xi.
[3] HDMA, *2002 HDMA Industry Profile and Healthcare Factbook*, 2002, p. xi.

34. The role of pharmacies and providers in the pharmaceutical market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11] as follows:

> The final step in the channel of distribution for pharmaceuticals comes when the pharmacist or physician provides the drug to the patient. In most cases, except for mail order pharmacies, this provision of the drug to the patient results from a face-to-face encounter with the patient. In addition to providing the drug product, the pharmacist is also responsible for taking steps to assure safe and effective drug use such as: development of a patient profile to screen for drug interactions, contraindications, and duplicate therapy; counseling the patient on appropriate use; and other similar activities. The physician has similar responsibilities and, in most Part B cases, administers the drug in conjunction with other services.
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> There are a number of types of pharmacies and providers as shown in Exhibit 4 [*Attachment 2 in this report*]. Community-based pharmacies accounted for the largest share (52.6 percent or $113.3 billion) of manufacturer prescription drug sales in 2002. Community pharmacy includes traditional chain pharmacies (e.g., Walgreen's or CVS), mass merchant pharmacies (e.g., Wal-Mart or K-Mart), food and drug pharmacies (e.g., Kroger or Safeway), and independent pharmacies (i.e., locally-owned corner drug stores). Mail order pharmacies accounted for 13.3 percent ($28.7 billion) of manufacturer prescription drug sales in 2002.
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> Health plan pharmacies purchased only 1.0 percent ($2.3 billion) of all prescription drugs sold by manufacturers. These purchases were made by managed care plans (HMOs and PPOs) with their own in-house pharmacies where the health plan takes possession of drug product inventory and dispenses prescriptions directly to patients. The vast majority of managed care plans contract with a network of community pharmacies for provision of prescription drugs or with a pharmacy benefit manager (PBM) to administer the benefit for the managed care plan.
>
> Other endpoints to the channels of distribution include: clinics and physicians' offices (1.0 percent; $2.3 billion); long term care pharmacies (4.4 percent; $9.5 billion); hospital pharmacies (15.9 percent; $34.3 billion); and government facilities and other government programs (4.4 percent; $9.6 billion).

B. Sources of Payment

35. There are three basic sources of payment for prescriptions: (1) self-pay or cash-pay individuals, (2) private third party insurance coverage, and (3) public (government) third party insurance coverage. The role of each source of payment in the prescription

drug market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11] as follows:

> Payments for prescription drug products may come from one, or more, sources including: the patient as an individual (termed "self-pay" or "cash-pay"); private insurance; public insurance (Medicaid and Medicare); or government delivered and financed health care. Various prescription drug programs are managed by Pharmacy Benefit Managers (PBMs) and engage networks of pharmacies and providers to deliver prescription drugs. [*See Attachment 3 in this report*].

36. The payment for prescriptions through cash or self-pay by individuals was discussed in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12] as follows:

> Self-pay, or cash, prescriptions represent a shrinking part of the outpatient prescription market. In 1992, more than one-half (55.6 percent) of all outpatient prescriptions were self-pay. By 1997, self-pay prescriptions had shrunk to 29.1 percent and in 2002 and 2003 they represent less than 15 percent of outpatient prescriptions. The dramatic reduction in cash pay prescriptions has also greatly reduced the pharmacy's pricing flexibility. The pharmacy has some control over setting the price for cash pay prescriptions, but it has little control over the prices paid by public and private third party programs. Although mail order programs, private PBMs and drug discount cards all claim to compare their prices against usual and customary retail prices, the disappearance of the cash pay retail prescription market renders the concept of "usual and customary retail price" almost meaningless.

37. The payment for prescriptions by private third parties (e.g., insurance and managed care) was discussed in my report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12] as follows:

> The share of outpatient prescriptions covered in part, or in whole, by private third party programs has grown substantially over the past decade from 30.1 percent in 1992 to 73.0 percent in 2002 and 2003. Most of these third party prescriptions are managed through PBMs and networks of pharmacies that have contracted to participate in these networks. Most pharmacists report that PBMs have most of the negotiating power in these networks, especially given their growing market share and the dominance of a few large PBMs.

38. The payment for prescriptions through public third parties (e.g., Medicare and Medicaid) was discussed in my report to CMS titled [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12-13] as follows:

> The Medicaid program is the single largest third party program (public or private) for prescription drug coverage. In 1992, Medicaid paid for 14.3 percent of all outpatient prescriptions and by 1997 the Medicaid share had dropped to 11.7 percent. The Medicaid share of outpatient prescription(s) has grown again over the last five years to 13.0 percent of outpatient prescriptions. Medicaid recipients in some states may pay modest co-payments. However, under certain circumstances if the patient can not pay the copay the pharmacy may still be required to dispense the prescription and the pharmacy may not be able to recover the lost copay from either the patient or the Medicaid program.
>
> Part B of Medicare paid for approximately 4 percent of total prescription drug expenditures in 2002. Once the MMA prescription drug benefit is implemented (January 1, 2006), Medicare (Parts B and D) will become the single largest third party program easily surpassing the Medicaid program. Medicare Part B beneficiaries are currently responsible for 20 percent of the cost of their covered medication, a sum that may be a substantial burden in cases in which beneficiaries do not have other insurance.

39. Collectively, third party prescriptions (private and government, such as Medicaid) grew from 70% of the prescription dollars and 67% of the prescriptions in 1996 to 91% of the prescription dollars and 89% of the prescriptions in 2005. With the institution of the Medicare Part D prescription drug program in 2006, the public third party share of the source of payment for prescriptions had a substantial jump, with all third parties (private and public) now covering the vast majority (greater than 92%) of all prescriptions. [National Association of Chain Drug Stores (NACDS), *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006]. Conversely, the share of prescriptions

paid for entirely by cash or the individual shrank to well under 10% of all prescriptions in 2006.

V. OVERVIEW OF PHARMACEUTICAL PRICING

40. There have been a number of signals raising concern over drug prices in the pharmaceutical market in recent years (i.e., since 2001). These signals regarding pricing behaviors in the pharmaceutical market were succinctly described in my 2004 report to CMS that was titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 2] as follows:

> A number of signals in the market have raised concern about prescription drug prices and expenditures to the top of the public policy agenda. First, outpatient drug expenditures in both public and private programs have been growing at an annual rate of 15 to 20 percent since the mid-1990s—a rate that is more than double the rate of growth in total health spending (i.e., Medicaid total expenditures grew 7.7 percent per year from 1997 to 2000).[4] Second, prescription drugs are the fastest growing sector of Medicaid programs, which, in turn, are one of the largest segments of state spending at a time when states are facing record deficits.[5] Third, the prices paid for prescription drugs by the Medicaid and Medicare programs have come under question compared to the prices paid by other sectors of the market.[6] For example, most other government programs (i.e., the Veterans Administration, and the 340B program for federally qualified facilities) pay less for prescription drugs than do the Medicaid or Medicare Part B programs, even after accounting for rebates.[7] Fourth, there is evidence that drug manufacturers have 'gamed' the pricing policies of both Medicare Part B and the Medicaid drug rebate program in a manner that creates economic incentives that lead to increased rather than decreased drug

[4] Gencarelli, Dawn M., Medicaid Prescription Drug Coverage: State Efforts to Control Costs, National Health Policy Forum, George Washington University, NHPF Issue Brief No. 790, May 10, 2003.

[5] Lav, Iris J. and Johnson, Nicholas, "State Budget Deficits for Fiscal Year 2004 are Huge and Growing," Center on Budget and Policy Priorities, revised January 23, 2003; accessed February 3, 2003, at http://www.cbpp.org/12-23-02sfp.pdf.

[6] US House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Subcommittee on Oversight and Investigations, Hearing, September 21, 2001.

[7] Schondelmeyer, Stephen W. "Estimated Relative Price Compared to AWP for Prescription Drugs at Manufacturer Level," Chart 4, p.10 as found in von Oehsen, William H., III, Ashe, Marice and Duke, Kathryn, Pharmaceutical Discounts Under Federal Law: State Program Opportunities, Public Health Institute, Pharmaceuticals and Indigent Care Program, Oakland, CA, May 2001.

> expenditures.[8,9,10] Fifth, legislation to cover outpatient prescription drugs under Medicare has recently been passed by the U.S. Congress and is set for an ambitious implementation schedule over the next year and one-half.[11]

41. The prescription drug market is characterized by "reverse, perverse economics" stemming from, *inter alia*, the following facts: (1) this is not a normal supply and demand market, (2) the vast majority of prescriptions are paid for by third party payers, and (3) different players in the system decide what medication is needed (the physician) and which particular medication is dispensed (the pharmacist), as well as which drug products are preferred (the PBMs), and all of these players are different from the ultimate payer (employer, government or individual) or the patient. There is little price transparency at most levels of the market. The third party reimbursement system has even led certain participants in the market to prefer the establishment and maintenance of high prices in various sectors of the market for their own benefit and to the detriment of the ultimate payer or patient.

42. Observation of prices in the pharmaceutical market requires an understanding of the elements, or attributes, that define a specific drug price term and an awareness of the sources of variation in price in the market.

A. Elements and Attributes of Drug Pricing Terms

43. There are several important and essential elements, or attributes, to any drug price that must be understood in order to know the meaning of a specific price for a specific drug product. These elements of a drug price were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*

[8] "2 Drug Makers to Pay $875 Million to Settle Fraud Case," New York Times, Oct. 4, 2001.
[9] "AstraZeneca Pleads Guilty in Cancer Medicine Scheme," New York Times, June 21, 2003.
[10] "Bayer Agrees to Pay U.S. $257 Million in Drug Fraud," New York Times, April 17, 2003.
[11] "Medicare Bills Would Add Drug Benefits: Prescription Drug Benefit Is Key To Biggest Changes in 38 Years," Washington Post, June 27, 2003, p. A01.

[Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 13-14] as follows:

> * ***list or transaction***: list prices are published by manufacturers; transaction prices stem from actual transactions and hence represent both the supply and the demand side of the market;
>
> * ***level of the market involved***: drug product transactions occur at different levels in the market such as the manufacturer, wholesaler, or provider (e.g., pharmacy, physician, hospital, etc.) levels;
>
> * ***classes of trade eligible for the price***: providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc) and the manufacturer's average selling price usually varies across classes of trade;
>
> * ***type of drug product***: drug products may be grouped by their patent and exclusivity status into three broad groups that have different pricing patterns such as single source (patent and exclusivity protected brands), innovator multiple source (off-patent brands), and non-innovator multiple source (generics or branded generics) drug products;
>
> * ***adjustments to price that have or have not been taken into account***: the invoice price for drug products may not reflect all adjustments to prices such as discounts, rebates, purchasing allowances or other forms of economic consideration;
>
> * ***source of the price information***: price information can be collected from different sources such as the manufacturer, wholesaler, provider, or a third party program;
>
> * ***effective time when price is available***: manufacturers determine when and how much the price of a drug product will change and the providers' costs are affected by price changes immediately upon implementation of a price change. The timing of when third party programs update their price reimbursement files (e.g., immediately or based on retrospective data) can have a substantial impact on providers; and
>
> * ***relationship to other prices***: AWP and WAC are primarily used as benchmark prices rather than as actual transaction prices, but most other types of prices, discounts, rebates, and methods of third party reimbursement are expressed in relationship to one of these benchmark prices (AWP or WAC).

B. Description of Key Drug Pricing Terms

44. There are several key drug price terms commonly used in the prescription pharmaceutical market in the United States. Discussed here will be the terms: wholesale

acquisition cost (WAC), average wholesale price (AWP), direct price (DP), earned discounts, and actual acquisition cost (AAC). These pricing terms as they have been used in statute or regulation related to Medicaid, Medicare or other third party programs, as well as other drug pricing terms that serve more specialized roles, are discussed elsewhere in this report. These drug pricing terms in the context of 2004 were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 14] as follows:

> ***Wholesale Acquisition Cost (WAC).*** The Wholesale Acquisition Cost (WAC) is a list price used for invoices between drug manufacturers and wholesalers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The WAC is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers have other names for this price such as list price, catalog price, or book price. In the past decade, WAC was a term that typically included adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. More recently, WAC has come to mean a list price before any form of price adjustment. WAC is closer to wholesaler's actual acquisition cost than is AWP. However, due to different levels of discounts across drug products and specific classes of trade, the WAC does not generally have a reliable relationship to the actual acquisition cost. Within a specific class of trade, WAC may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. If WAC is to be used to estimate a price from wholesaler to provider (i.e., pharmacy, physician, or others), an adjustment must be made to account for the wholesaler (or chain warehouse) operating cost and a reasonable profit.
>
> ***Average Wholesale Price (AWP).*** The Average Wholesale Price (AWP) is a list price used for invoices between drug wholesalers and pharmacies or other appropriate drug purchasers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is set directly, and published, by most drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers argue that they do not set the AWP, but instead either the wholesaler or the drug price databases set the AWP. Even when the AWP is actually calculated by a wholesaler or a drug price database, these sources typically calculate the AWP as a fixed percentage above the WAC (i.e., typically 20 or 25 percent above WAC for brand name drugs) so

that, in effect, by setting the WAC the drug manufacturer also sets the AWP for a drug product. AWP has been a term that typically does not include adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is typically 20 to 25 percent above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs. Because of different levels of discounts across drug products and specific classes of trade, the AWP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, AWP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.

Direct Price (DP). The Direct Price (DP) is a list price used for invoices between drug manufacturers and pharmacies or providers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The DP is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Many drug manufacturers have a wholesale only policy and do not sell directly to pharmacies or providers, while other drug firms establish a direct price and do sell drug product directly. Direct purchases are often subject to minimum order quantities and, therefore, direct purchases may not be practical or economically efficient for many purchasers.

Certain direct purchasers (i.e., physicians, but typically not pharmacies) may benefit from delayed invoice dating (e.g., payment is not due for 60 or 90 days) from the manufacturer. The DP for some manufacturers is the same as the WAC, while for others the DP may be slightly higher (by 3 to 5 percent) than WAC. Because of different levels of discounts across drug products and specific classes of trade, the DP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, DP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. However, use of direct price to estimate pharmacy or provider acquisition cost must take into account the added cost of acquisition. A larger share of generic drugs, than of brand-name drugs, is sold direct from the manufacturer. Because of different levels of discounts, the DP does not have a reliable relationship to the actual acquisition cost, in general, or for specific classes of trade.

Earned Discounts. Earned discounts are transactional discounts based on efficient business practices of the pharmacy or physician purchasing drug products from either a wholesaler or a drug manufacturer. The earned discount is usually expressed in terms such as '2-10 Net 30', meaning 2 percent discount off of the total invoice amount if paid within 10 days and the full invoice amount is due if paid between 11 and 30 days. Earned discount terms are set by the wholesaler or the manufacturer and are usually stated on the invoice. In some cases, manufacturers offer substantially greater delayed invoice payment to certain classes of trade (e.g., direct physician purchasers) that allow the purchaser to sell and collect for the drug product before the payment to the manufacturer is

> due (e.g., payment is not due for 60 or 90 days). These greatly delayed invoice terms would not typically be called 'earned discounts'. Different levels of 'earned discounts' and 'other delayed term discounts' are available to different classes of trade. The earned discounts will usually have a reliable relationship to actual acquisition cost, but not necessarily to AWP or WAC. The treatment of earned discounts in estimating actual acquisition costs of a pharmacy or provider should be consistent with the actual payment terms of a given third party when reimbursing pharmacies or providers.
>
> ***Actual Acquisition Cost (AAC).*** The Actual Acquisition Cost (AAC) is a transaction price used to describe the price paid by a pharmacy or provider when purchasing a drug product from either a drug manufacturer or wholesaler. The invoice price and all on-invoice, as well as off-invoice, adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration are taken into account. This price is the appropriate conceptual basis for the payment policy.
>
> The AAC is set by the drug manufacturer, but, historically, has not been published or made public. Some drug manufacturers may have a variety of terms for specific discounts that are based on class of trade, volume of purchase, market share movement, preferred formulary status, terms of payment, bundling of products, and other criteria. AAC is meant to be the net price after all forms of discount, rebate, purchasing allowances or any other forms of economic consideration have been taken into account. Arguably the discounts that contribute to AAC are considered proprietary and confidential by drug manufacturers. Consequently, the relationship of AAC to either AWP or WAC is not predictable from public data sources in general, or for specific classes of trade. For single source brand name drugs that do not typically have discounts beyond on-invoice 'earned discounts', the AAC may have a reasonably predictable relationship to AWP or WAC.

45. The definition and understanding of these, and certain other drug price terms, should be viewed in historical perspective and in context. As noted above, for example, in the context of the compendia that have been used as public sources of pricing information, AWP came to be used as a reference to the price on invoices from the wholesaler to the pharmacy. I am also aware that Judge Saris has examined the meaning of the term AWP in the Medicare context and determined that the term should be given its plain meaning in accordance with established principles of statutory construction. The historical context should also be considered; for example, in the early 1990s, a report to HCFA (now CMS) on the adequacy of reimbursement rates to pharmacies provided a

definition of key drug pricing terms. [Adams, Kathleen and David H. Kreling, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4].

46. This 1993 report to HCFA on pharmacy reimbursement defined the following drug price terms:

> * Actual Acquisition Cost (AAC) – Pharmacist's net payments made to purchase a drug from any source (e.g., manufacturer, wholesaler) net of discounts, rebates, etc.
> * Estimated Acquisition Cost (EAC) – An estimate of pharmacies' actual acquisition costs that are made by the States and other third-party payers.
> * Maximum Allowable Cost (MAC) – A maximum dollar amount for which the pharmacist is reimbursed for selected products.
> * Average Manufacturer's Price (AMP) – The average price paid by wholesalers to manufacturers for products to be distributed to retailers.
> * Average Wholesale Price (AWP) – The manufacturer's suggested wholesale price to the retailer which is listed in either the Red or Blue Book.
> * Wholesale Acquisition Cost (WAC) – The wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.
>
> [Adams, Kathleen and David H. Kreling, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4].

47. In this 1993 report to HCFA, the term 'actual acquisition cost' had essentially the same meaning as it did in the 2004 report to CMS. That is, AAC represents the net transaction price paid by a pharmacy or provider. Similarly, the AWP as described by the authors of both reports is a price reported, directly or indirectly, by the drug manufacturer as the suggested price from the wholesaler to the retailer. The relationship of AWP to actual transaction prices, however, has not been consistent over time or across types of drug products, such as the use of this term with respect to brand name and generic drug products.

48. Notably, the definition of WAC appears to have changed over time. In 1993 WAC was, or was believed to be, "the wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts." [Adams, Kathleen and David H. Kreling, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4]. By 2004, however, WAC had come to be viewed as a benchmark price for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration [MMA; Pub.L. 108-173].

49. The term 'estimated acquisition cost' was defined in the 1993 study for HCFA as a price intended to be an estimate of the pharmacy's actual acquisition cost. The Medicaid program has consistently defined estimated acquisition cost as a price concept that provides a method to estimate the 'actual acquisition cost' to the pharmacy or provider, as described in a later section. This consistent definition of 'estimated acquisition cost' as an estimate of the pharmacy's actual acquisition cost was first defined by Medicaid as far back as 1977 and continues to be defined in the same way as recently as 2007.

C. Definition and Determination of Estimated Acquisition Cost (EAC)

50. Actual drug transaction prices in the market are not readily available to third party payers, including government entities, on a routine basis, and audits to gather that information are extremely expensive and time-consuming and frequently result in outdated and incomplete information. Consequently, the development of a price database

for payment and reimbursement of prescription drugs requires some means of estimating acquisition cost for drug products on an ongoing basis.

51. The estimated acquisition cost was developed as a way to simplify payment for prescriptions in a manner that was consistent with the Medicaid program's intent to pay the actual acquisition cost for a given prescription drug or as close to the actual acquisition cost as is feasible. Determining the actual acquisition costs of every prescription would require auditing literally tens of thousands of prescription drugs on the market and the price of each drug product to each pharmacy for every time a purchase is made. Such an audit of actual acquisition costs would be extremely difficult, complex, and very time-consuming and expensive. Use of audited actual acquisition costs was simply not feasible.

52. The Medicaid program chose to base prescription payments on "estimated acquisition cost." The intent and definition of estimated acquisition cost dates as far back as 1977 as described in an HHS document titled, "Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." This HHS memo to state Medicaid directors stated "The intention of the final Medicaid regulations on drug reimbursement is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14].

53. The term "estimated acquisition cost" (EAC) was further defined as "the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers." [42 CFR Part 447.301; see Fed Reg, Vol. 52, No. 147, July 31, 1987, pp. 28648-58.] This description of EAC was reported in the Medicaid compendium titled *Pharmaceutical Benefits Under State Medical Assistance Programs* (NPC Medicaid Book) and published by the National Pharmaceutical Council (NPC). This description of EAC, emphasizing that this term is supposed to represent a price that is "as close as feasible to the price generally and currently paid by the provider" or a similar statement, has been reported in every annual volume of the NPC Medicaid Book from 1979 to 2007. [For example, see NPC, *Pharmaceutical Benefits*, 1991, p. 51.; 1994, p.14; 1999, p.4-55].

54. California regulations define estimated acquisition cost as "the Department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." [Cal. Code Regs. tit. 22 §51513(a)(6), effective 3-1-95]. This definition is very similar to the one contained in federal regulation.

55. Because transaction prices were not readily available in the marketplace and the AWP was the only price available for all, or virtually all, drug products, most public and private third party programs use AWP prices, or adjusted versions of this price, as their means of estimating acquisition cost for drug products. In other words, most private third party and government payers set their payment formulae for estimating drug product costs as either a certain percent discount off of wholesale to retail prices (AWP) or in some cases as a certain percent above the price from manufacturer to wholesaler (WAC).

56. The potential methods for states, or CMS, to estimate or determine market prices for prescription drugs were evaluated in a research project I conducted with colleagues from Abt Associates, Inc. for the Centers for Medicare & Medicaid Services in 2004. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 1-70 plus Appendices].

57. In conducting our study of methods to estimate acquisition costs for pharmaceuticals, we set forth several criteria that would assist in determining the validity and reliability of the estimation method. Ideally, the method used for determining "estimated acquisition cost" should produce cost information for each drug product with prices that are: accurate and reliable, generally and widely available, current and up-to-date, transparent and accessible, adequate compensation to providers and pharmacies, incentives for pharmacies and providers to supply drugs, and incentives for key parties to provide data. The nature of each of these criteria, as discussed in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 18-19], is discussed briefly:

> **Accurate and Reliable**
> The Medicaid and Medicare programs should have access to accurate and reliable information regarding the actual acquisition costs for prescription drugs for each channel of distribution. Based on such accurate and reliable cost data, these programs may decide that the payment rate to pharmacies or physicians should include a percent markup on brand name drug product costs, and an even greater markup for generic drugs, but this practice should be an explicit decision of the policy maker and not an implicit and hidden factor left in the control of the pharmaceutical manufacturer. In this context, 'accuracy' concerns the degree to which the price used in payment policy is close to, or the same as, the amount actually paid by a pharmacy or physician for a given drug product. 'Reliability' is the degree to which the price used in payment is consistent for similar prescription claims. Based on Markets: Estimated acquisition costs are more likely to be accurate if they are based on actual transaction prices in the market (i.e., the average selling price). Market or actual prices can be contrasted both to list prices, set by manufacturers, and to administered prices, set by the government. This approach, however, requires transparency of transaction prices.

Generally and Widely Available

Any price list used by the Medicaid or Medicare program should reflect 'generally and widely available prices,' that is, any (prudent) provider paid according to the payment policy should be able to procure drugs at the published payment amount. Estimated Separately by Class of Trade: Because actual acquisition costs vary by class of trade, the estimation methodology must take into account these differentials in order to generate drug product payments that are both accurate and reflect generally and widely available prices. For example, when a drug manufacturer sets lower prices for one class of trade (e.g., physicians) versus another class of trade (e.g., community pharmacies), the result is that the average of the prices across these two classes of trade will overpay the class with the lower price (physicians) and will under pay the class with the higher price (pharmacies). In addition to class of trade differences, drug product prices may differ for other reasons such as geographic or regional (urban versus rural) variations. A payment policy that does not account for different acquisition costs by class of trade, or other factors, may preclude certain providers from the market for reasons beyond their control. For providers within the same class of trade, the concept of 'generally and widely available prices' is appropriate and helpful to assure that a wide spectrum of physicians or pharmacies will be willing to participate in the program.

Current and Up-to-Date

An effective price list must be based on current prices that are updated regularly. Drug prices are set by drug manufacturers and can change whenever the manufacturer decides to adjust the price (usually an increase). Most manufacturers change drug product prices every 6 to 12 months with the average interval being about 10 to 11 months, however, some drug products may change their prices much more frequently. Claritin, for example, in the last three years before being switched to over-the-counter status raised its price every three months and had a cumulative annual price increase in 2002 of 21.2 percent. If provider payments for prescription drugs were being revised only once a year, a pharmacy would be losing as much as 20 percent on each Claritin prescription dispensed near the end of the year.

An effective payment policy should not set drug product payment amounts that consistently result in an underpayment due to delayed updates of prices. The drug product payment database needs to be electronically available using the standard electronic data interchange protocols in the prescription marketplace, and it needs to be updated on a virtual basis with a minimum of time delay (1 week or less) in updating price changes.

Transparent and Accessible

The price list and payment policy must be readily available to, and clearly understood by, market participants. Those covered by the payment policy should understand the source of data and how those data are translated into the payment policy. In addition, any price list to be used in payment for prescription drug products must be in an easily accessible and usable format. This format must be compatible with pharmacy and claims processor computer and software systems. Obviously, an electronic database is essential for both efficient publication and

use. Pharmacy and physician providers must be able to easily confirm current payment at the time of prescribing, or dispensing, a prescription.

Adequate Compensation to Providers and Pharmacies
While the drug product component of the payment policy should be based on actual acquisition costs, the payment policy as a whole should adequately compensate providers for the storage, handling, dispensing, and administration of prescription drugs and for their professional services. This is essential to ensure that beneficiaries have access to quality care, without triggering perverse incentives. At present, the margins, or spreads, between drug product payment amount and actual acquisition cost may compensate providers (physicians and pharmacies) for deficiencies elsewhere in the payment system. If and when the method for estimating acquisition costs is altered, it may be desirable to reconsider the payment policy as a whole.

Incentives for Pharmacies and Providers to Supply Drugs
Any payment scheme creates financial incentives for providers. Ideally, these incentives foster quality and cost-effectiveness. Two main dimensions of provider incentives have already been discussed. First, adequate compensation gives providers incentives to participate in the program and supports beneficiary access. Second, payment based on actual acquisition costs creates neutral incentives for providers regarding the choice of drug therapy with the result that providers are more likely to focus on the choice of therapy that is optimal for the patient and economically efficient for the program.

Incentives for Key Parties to Provide Data
Pricing data will be needed from various levels in the market to determine appropriate payment amounts. If the program establishes fair, but not excessive prices, providers will be more likely to participate in good faith than if the program tries to implement below-market prices that overly squeeze the provider's margins. In addition, terms must be clearly defined so that firms understand what data they are expected to submit and so that analysts understand what data they have received.

Authority to conduct audits of drug manufacturers and of all provider types may provide some incentive for firms to participate in reasonable requests for data. Other incentives need to be identified and examined. If manufacturer data submission is chosen as a viable alternative, the drug firm can be asked to certify the data provided in a manner similar to that specified in the corporate integrity agreements (CIAs) developed by the Department of Justice for use by those drug firms that have settled fraud allegations related to Medicaid and Medicare drug pricing.

58. The options evaluated in our research study for estimating acquisition costs for drugs covered under Medicaid or Medicare included: (1) collecting primary data from manufacturers, (2) careful analysis and evaluation of list prices over time, (3) use of secondary invoice price data such as that collected by IMS Health, (4) survey of

pharmaceutical wholesalers' prices, and (5) survey of pharmacies and other providers. Each of these options was evaluated by a panel of experts and was reviewed against the criteria mentioned above. The panel was composed of fifteen experts from various segments of the healthcare community in the United States, including physicians, chain drug stores, community pharmacies, other providers, state Medicaid agencies, drug wholesalers, database organizations, academia, and CMS.

59. The conclusion of this study to evaluate methods of estimating acquisition cost was as follows:

> There is no simple method of estimating acquisition costs. Based on our research and the comments of the Expert Panel, the authors recommend that CMS consider an approach to estimating acquisition costs that is based on collecting primary data from manufacturers. Members of the expert panel strongly favored this approach at the meeting and in their individual comments after the meeting.
>
> In particular, in addition to list prices, manufacturers would be asked to supply average selling prices by class of trade. These classes of trade might include independent pharmacies, chain warehouses, long term care pharmacies, physicians (direct sales), and hospitals. If these data are to be used as a basis for payment under Medicare Part D which begins in January of 2006, then prices to the mail order class of trade should also be collected. Manufacturers would also be asked to note other major provider types that might be purchasing on behalf of Medicaid and Medicare beneficiaries, to explain the situation, and to provide the associated average selling prices. All terms would be carefully defined including pricing terms, as well as discounts and rebates to be included and excluded, and the channels of distribution. Manufacturers would be required to certify that the prices supplied were true and accurate.
>
> The strengths of this approach are that it: (1) yields actual transaction prices, (2) incorporates all discounts and rebates, (3) incorporates class of trade differentials, (4) provides an efficient method (relative to a provider survey), and (5) represents a feasible approach to estimating actual acquisition cost. Similar methods are in place in the Medicaid rebate program and in the Texas Vendor Drug Program.
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> [Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, p. 28].

60. Based on the findings of the expert panel, and the experience of the researchers and panel members, a recommendation was made that "CMS undertake a careful

evaluation of the existing Texas Vendor Drug Program (VDP) and the price data that it collects." [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 29]. This recommendation was made because the Texas VDP approach to determining estimated acquisition cost was considered by the panel and the researchers to be "very similar to our recommended approach." CMS did fund the study to evaluate the Texas VDP approach to estimating drug acquisition costs and the findings of that study are reported in the next section.

D. Case Study of the Texas Vendor Drug Program

61. The Texas VDP (Medicaid) approach to estimating drug acquisition cost was the object of a study I conducted with colleagues at Abt Associates, Inc. on behalf of CMS in 2005. [Wrobel, Schondelmeyer, et al., *Case Study of the Texas Vendor Drug Program*, 2005, p. 65]. A previous study had indicated that Texas VDP appeared to have a system for estimating acquisition cost that was very similar to the optimal system recommended by a panel of experts. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 29].

62. The Texas Vendor Drug Program (Texas VDP) spent about $253 million on pharmaceuticals in 1991. By 2005, Texas VDP drug spending had grown nearly ten-fold to $2.475 billion. The annual rate of growth in drug spending for Texas VDP was at double-digit rates for every year, but one, between 1991 and 2005. Texas served about 2.7 million Medicaid enrollees in 2003 and provided nearly 35 million prescriptions.

63. The Texas VDP approach to estimating acquisition cost based upon manufacturer reported drug prices that were current and generally available net prices paid by pharmacies in the market was considered to be the most practical method of estimating

acquisition cost for purposes of determining appropriate reimbursement under a state Medicaid drug program. However, the Texas VDP reimbursement process, and programs such as Medi-Cal that rely upon commercial drug price databases, depended upon drug manufacturers to report prices that reasonably represented the actual net prices currently and generally paid by providers in the marketplace. [Deposition of Martha McNeill, July 12, 2007, p. 45, lines 19 to 24].

64. State Medicaid programs, such as California and Texas, have tried various approaches to improve their ability to estimate the acquisition cost of prescription drugs. The effectiveness of these prescription payment methods, however, is dependent upon having relevant, accurate, and timely information on prices from manufacturers, suppliers, pharmacies, or providers. (e.g., see Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, p. 260; Roxanne Homar (WY), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 3, 2008, p. 422; and J. Kevin Gorospe (CA), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 3, 2008, p. 253.)

65. Even though the Texas VDP implemented a system that directly requests actual (net) prices from drug manufacturers, some manufacturers including Dey, Mylan and Sandoz have not been reporting actual (net) prices. Consequently, Texas VDP has continued to pay more than it would have paid if it had accurate and reliable price information from those drug manufacturers and has resorted to litigation against companies including Dey, Mylan, and Sandoz to remedy the effects of their inflated price reporting.

E. Sources of Variation in Drug Prices

66. Drug prices will typically vary over time. Other sources of variation at any specific point in time may be related to: (1) the type of purchaser (i.e., also referred to as classes of trade), (2) the type of drug product, and (3) geographic variation. Each of these potential sources of variation is addressed briefly.

1. Class of Trade Variations in Drug Prices

67. The type of purchaser of a drug product may determine the price level that is available to that purchaser. The role of purchaser type was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 16-17] as follows:

> Nearly all drug manufacturers divide the channels of distribution into groups known as 'classes of trade'. The 'classes of trade' at the broadest level are the groups identified on the pharmacy-provider level of the channels of distribution chart (Exhibit 4) including: chain pharmacies, mass merchant pharmacies, food and drug pharmacies, independent pharmacies, mail order pharmacies, health plan and HMO (in-house) pharmacies, long term care pharmacies, hospital pharmacies, physicians and clinics, government facilities, and other settings. The structural differences in actual prices charged to each of these 'classes of trade' can differ considerably and appear to be arbitrary and are usually unrelated to volume of drug product purchased.
>
> In most markets, when one buyer can purchase a product at a lower price than other purchasers, there is the potential for arbitrage. That is, the buyer with access to the lower price is able to purchase the product at the low price and resell it, at a profit, to the party without access to the lower price. This drives down the price differentials both directly (because the high-price buyers get lower prices) and indirectly (because manufacturers no longer gain from the differential pricing and hence desist from the practice). This practice of arbitrage across classes of trade is explicitly prohibited by re-sale limitations established in the pharmaceutical marketplace by the Prescription Drug Marketing Act of 1988.
>
> Both the monopoly position of patent (or exclusivity) protected drug products and the prohibition on arbitrage enable drug firms to use 'discriminatory pricing', which seeks to maximize the price to each individual buyer or group of similarly situated buyers. There are sometimes volume discounts within a class of trade, but volume does not usually explain the difference in price across classes of trade. A physician purchasing drug product direct from the manufacturer will usually get one of the lowest prices in the market, especially for drug products administered in the physician's office, while independent and chain community

> pharmacies often pay the highest prices in the market. This pattern occurs even when the chain pharmacy purchases far more volume (millions of dollars) nationally than an individual physician purchases in a year (i.e., hundreds or thousands of dollars). Volume may get one physician a better price than another physician. Volume, however, does not explain why a chain pharmacy pays a higher price, even though it purchases a substantially larger volume of a drug product than an individual physician typically purchases. The structural barriers of monopoly position and statutory prohibitions on price arbitrage mean that the purchasers who get the lowest price in the market are not necessarily the most efficient purchasers in the market. Because class-of-trade differentials exist and are outside of the control of the purchaser, an accurate approach to estimating actual acquisition costs must take into account the class of trade pricing practices of drug firms. The practice of class of trade pricing is not usually disclosed directly by drug manufacturers and could experience change as the dynamics of the pharmaceutical marketplace evolve during the implementation and operation of the new Medicare outpatient drug benefit.

68. In summary, class of trade pricing operates based on structural criteria in the market and not necessarily efficiency-based criteria. In other words, the purchaser with the lowest purchase price may not be the purchaser with the largest volume of purchases. The 'class of trade' pricing practices are not usually disclosed by pharmaceutical companies.

2. Drug Product Type Variations in Drug Prices

69. The type of drug product with respect to patent status has an influence on drug product prices and relationships among various prices. The three major drug product types are: (1) brand name drug products with patent and/or other market exclusivity, sometimes referred to as single source (SS) drug products; (2) brand name drug products that have lost their patent and market exclusivity, also known as off-patent brands or innovator multiple source (IMS) drugs; and (3) off-patent generic drug products, also known as non-innovator multiple source (NMS) drug products.

70. The pricing patterns and relationships among prices may vary by type of drug product. Patented brand name, off-patent brand name, and generic drug products have different pricing patterns and these patterns are described in my 2004 report to CMS

[Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 17-18] as follows:

> The pricing patterns of brand name drug products and generic drug products can be quite different. For most brand name drug products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is reasonably predictable. That is, the WAC is equal to, or very close to (+ or – 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP is typically 20 to 25 percent above the WAC or, alternatively, WAC is 16.67 or 20 percent below AWP. In such cases, a payment policy based on AWP (i.e., usually AWP minus a certain percent) may be relatively accurate. This pricing pattern holds for community pharmacy classes of trade (independents, chains, and food & drug stores), but not necessarily for other classes of trade (i.e., mail order pharmacies, HMOs and health plan pharmacies, long term care, physicians or clinics, hospitals, or state and federal facilities or programs). Some of these other classes of trade control the demand (i.e., prescribe or influence the drug prescribed) and are reimbursed by a third party based on a percent off of AWP or a percent above WAC. When these other providers can actually purchase the drug product from the manufacturer, and when the manufacturer deliberately creates a large and hidden spread between actual acquisition cost and the reimbursement amount, then the physician or other provider has a very strong financial incentive to prescribe their drug. This non-transparent spread leads to a financial incentive to prescribe more often and to prescribe higher-priced drugs over lower-priced drugs even when they are not necessarily the most cost-effective alternative. These financial incentives from the hidden spreads may be one factor contributing to the rapid growth of Medicare Part B drug program expenditures over the past four years.
>
> Once a brand name drug product loses its patent and market exclusivity, the brand name drug may face price competition from generic versions of the drug product. Usually the brand manufacturer does not compete on price with generics for the community pharmacy class of trade. This means that the AWP and WAC relationship to actual acquisition cost discussed earlier for brand name drugs still holds. However, brand manufacturers sometimes offer substantial discounts relative to WAC to certain classes of trade (i.e., hospitals, long term care, health plans, and physicians). This may keep the actual acquisition cost of the brand drug somewhat price competitive in non-community pharmacy settings, and particularly when the provider receives payments keyed to list prices may result in excessive financial incentives to prescribe or use the brand name rather than a generic equivalent.
>
> Price competition begins when the market is entered by the first generic drug product that is a therapeutically equivalent version of a brand name drug product made by the drug firm that holds the original NDA for a given chemical entity. When two or more generic drug products enter the marketplace they typically compete on price with each other even though the brand name product usually does not compete on price. The first generic will typically enter the market at a list price (both AWP and WAC, if a WAC is reported) that is 10 to 30 percent

> below the originator brand price. Often the price competition among generic versions of a drug product will be reflected by one or two decreases in list prices (AWP and WAC) in the first six to twelve months after generic entry, but after that time it is rare to see generic list prices change and at some point in time the generic list prices for some drugs may even begin to rise again.
>
> The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWPs that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition cost for generics. Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts in lower AWP or WAC list prices. Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs. Medicaid drug payment policy reflects the lower market prices for generic drugs by placing a FUL (a federal MAC or a state MAC) on many generic products.

3. Geographic Variations in Drug Prices

71. The price of drugs may arguably vary by geographic region. However, for the most part, the purchase of prescription drugs from manufacturers and wholesalers functions primarily at a national market level. My research report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 18] discussed geographic variation as follows:

> Geographical variations in the actual drug cost at the manufacturer level are not common. Once one has accounted for class of trade differentials, most drugs have the same list prices (AWP and WAC) regardless of where they are purchased or used. In the few cases where a specific drug may have prices that vary by region, the variation is often in response to certain third party payment methods (i.e., the Least Costly Alternative (LCA) method) of paying for therapeutic alternates under Medicare Part B by certain fiscal intermediaries.
>
> In contrast to the general uniformity of prescription drug prices, the cost of professional services (i.e., physician fees or pharmacy fees) usually varies by geographic region. Both physician and pharmacy costs of providing the required services that accompany prescription drugs vary by geographic region due to differences in rent, salaries, general cost of living, insurance, and other factors. To the extent that the drug cost component of the payment policy is intended to also cover part, or all, of other costs associated with drug provision (e.g., storage and handling, or counseling and medication therapy management), there may be a need for this component to vary by region. Also, for the reasons above, changes in drug product payment policy may have different impacts upon

providers and pharmacies across regions. These same factors may also vary across geographic locations (rural versus urban) within the same region.

VI. THE MEDICAID DRUG PROGRAM

72. The Medicaid drug program dates back to 1965 when the U.S. Congress created Medicare and Medicaid out of the varying state programs to provide health care to the aged and indigent, respectively. Prescription drug coverage is an optional service in Medicaid, but virtually all states offer a prescription drug benefit. The Medicaid program is jointly funded by federal and state resources based on a cost sharing formula, with various federal shares across the states ranging from 50% to 75% of total drug program costs. Both Medicaid and Medicare now have prescription drug benefits that serve, respectively, the indigent and the elderly and disabled. The public financing for prescription drug coverage of these populations has provided increased access for many persons who could not otherwise afford necessary drug therapy. Drug manufacturers have benefited from this increased coverage and market expansion through increased drug sales financed by public programs such as Medicaid and Medicare.

73. Medicaid expenditures are usually one of the largest items in the state's budget. In addition, Medicaid expenditures have been one of the fastest growing components of the state budget and Medicaid drug expenditures have been one of the fastest growing pieces of Medicaid. For these reasons, among others, state Medicaid agencies attempt to use state resources as wisely and efficiently as is possible given the resources available.

74. My experience in working with state Medicaid programs over the years has been that the state agencies do their best to estimate actual acquisition costs for covered drug products. Efficient and appropriate use of Medicaid drug program resources enables the

state government to accomplish other policy objectives such as ensuring increased access to care, coverage of more beneficiaries, encouragement of lower cost generic drug products, incentives for utilization of least costly alternatives for treatment, and minimization of program administrative costs. Medicaid drug program resources can be used more efficiently and appropriately with drug price information that is reliable, accurate, comprehensive, and timely. The staff of state Medicaid agencies, when carrying out their responsibilities, attempt to do their best to estimate the actual acquisition cost of drug products in the market given the resources available. [Deposition of Stan Rosenstein, *California ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 03-CV-11226-PBS, November 6, 2008, pp. 300-302; Deposition of Martha McNeill, July 12, 2007, p. 39, lines 15 to 20; p. 27, line 24 to p. 28, line 5]. The ability of state Medicaid programs to implement their chosen policy objectives and to manage resources efficiently is negatively impacted by the provision of inflated price information by drug manufacturers, including Dey, Mylan, and Sandoz. [For example, see Deposition of Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 241-244; Deposition of Stan Rosenstein, *California ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 03-CV-11226-PBS, November 6, 2008, pp. 302-305.]

75. Overall, Medicaid drug expenditures accounted for 12.1% of total outpatient drug expenditures in the U.S. in 1996, and reached a high proportion in 2004 at 15.3% of total outpatient drug expenditures. The number of Medicaid prescriptions represented 11.6% of all outpatient prescriptions in 1996 and grew to their highest share in 2004 at 13.6%. [NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for

1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006].

76. Medicaid outpatient prescription drug expenditures in the U.S. were $4.4 billion in 1990 and they had nearly doubled in six years (1996) to $8.7 billion. In the next nine years (1996 to 2005), Medicaid outpatient prescription expenditures nearly quadrupled to $32.1 billion. [NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006].

77. The growth of Medicaid drug spending was at double-digit rates for most of the period from 1990 to 2005. [NPC, *Pharmaceutical Benefits*, annual editions from 1990 to 2005/2006].

78. At the national level, the Medicaid drug expenditures grew 221% from 1992 to 2002 (in constant dollars). Total drug expenditures were broken down into several contributing components: number of drug recipients, drug utilization (prescriptions per person per year), manufacturer drug product cost and pharmacy fees. Over the decade from 1992 to 2002, the number of drug recipients decreased about 6% and drug utilization increased 46.8%. The average payment per prescription grew more than 107%, with the manufacturer drug product cost increasing 137% and the pharmacist's fee declining 20%, in constant dollars. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 4-5].

79. Medicaid has historically been the single largest payer for prescription drugs in the United States—although with the advent of the Medicare Part D prescription drug program in 2006 that role has now been supplanted.

80. The Medi-Cal drug program experienced changes in the same direction as those observed at the national level. Medi-Cal outpatient prescription drug expenditures were $0.56 billion in 1990 and they more than doubled in five years (1995) when Medi-Cal covered about 49 million prescriptions and which accounted for an expenditure of more than $1.2 billion at an average prescription price of $23.51. By 2005 Medi-Cal paid for 52 million prescriptions at a total expenditure of $4.6 billion. Beginning in 2006 the prescription drug coverage for dual eligible elderly beneficiaries was moved from Medi-Cal to the new federal Medicare Part D prescription drug program. Consequently, the drug expenditures under Medi-Cal decreased substantially in 2006 compared to 2005. The Medi-Cal drug expenditures in 2006 were $2.4 billion for 27 million prescriptions—nearly one-half of the 2005 levels. The average Medi-Cal prescription price in 2005 was $88.21 and in 2006 was $88.99. [NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006].

81. The sources of growth in the Medi-Cal drug program were examined for the period 1992 to 2002. Total Medi-Cal drug expenditures, in inflation adjusted dollars, grew 205% from 1992 to 2002—a tripling in expenditures. The number of Medi-Cal drug recipients decreased by 20% over the same time period while the drug use rate increased nearly 50% and the average prescription payment increased 156%. Growth in

the average Medi-Cal prescription price was driven entirely by an increase of 198% in the manufacturer's drug ingredient cost, while pharmacy dispensing fees over the same time period decreased 22% in inflation adjusted terms.

82. The growth of Medi-Cal drug spending was at double-digit rates for all but three of the years from 1990 to 2004. [NPC, *Pharmaceutical Benefits*, annual editions from 1990 to 2007].

A. Medicaid Drug Reimbursement

83. The state Medicaid programs reimburse for covered pharmaceutical products through various formulas that are designed to estimate the acquisition cost of the drug product to the provider submitting the claim for reimbursement. Medicaid programs, then, determine the amount to pay on a specific claim for prescription pharmaceuticals by setting an amount intended to compensate the provider for the estimated acquisition cost of the drug product plus an additional amount, also set by the applicable Medicaid reimbursement method, to compensate the provider for overhead related to the cost of dispensing prescriptions and counseling patients and a reasonable profit.

84. Pharmacy and provider payments for prescription drugs are set using similar basic payment formulae set by federal statutes and regulations and applied in all states. Individual states may, then, modify or add other factors in the payment process with the approval of the federal agency, CMS. The basic parameters of the reimbursement formula are specified in federal regulations as described in the paragraph below:

> **History:** Federal Medicaid regulations dictate the method for reimbursing prescription drugs. Reimbursement is made on a retrospective, fee-for-service basis with payments limited to the lower of the pharmacy's usual and customary charge or the estimated acquisition cost of the drug product plus an established dispensing fee to cover the pharmacy's overhead and profit. (Some states have experimented with enrolling Medicaid eligibles in Health Maintenance Organizations under capitated payment contracts.) In 1976, utilizing the authority

> to set an upper limit for services available under Medicaid programs as provided under Section 1902(a)(30)(A) of the Social Security Act, the Health Care Financing Administration (HCFA), HHS implemented drug reimbursement rules at 45 CFR Part 19 pertaining to upper payment limits for Medicaid and other programs. Specifically, these regulations provided that the amount the Department recognized for drug reimbursement or payment purposes was not to exceed the lowest of:
>
> - the maximum allowable cost (MAC) of the drug as established by HCFA's pharmaceutical reimbursement board for certain multisource drugs (generic drugs), plus a reasonable dispensing fee;
> - the estimated acquisition cost (EAC) of the drug (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers), as determined by the program agency, plus a reasonable dispensing fee; or
> - the providers' usual and customary charge to the public for the drug.
>
> [NPC, *Pharmaceutical Benefits*, 1993, p. 15].

85. Importantly, note that the payment to the provider is the "lower of" the various prices including: (1) the pharmacy's usual and customary charge for the prescription; (2) the estimated acquisition cost (e.g., AWP –X%) for the drug product plus a dispensing fee; or (3) the federal upper limit (FUL), or state maximum allowable ingredient cost (state MAIC), for certain generic drug products plus a dispensing fee.

86. Specifically, the Medi-Cal program uses the price information from manufacturers obtained from the commercial price database in a formula to determine, among other things, the cost of the drug product which is the lowest of: "the Estimated Acquisition Cost (EAC), the Federal Allowable Cost (FAC) [also known as the Federal Upper Limit (FUL)], or the [state] Maximum Allowable Ingredient Costs (MAIC)/Maximum Allowable Product Cost (MAPC) for the Standard Package size… The price charged to the program shall not exceed that charged to the general public." [Cal. Code Regs. Tit. 22 §51513(a)(13), effective 3-1-95; see also Cal. Code Regs. tit. 22 §51513(b)(1)(A), effective 3-1-95].

87. State Medicaid programs have to file a State Plan with CMS under Title XIX of the Social Security Act. This State Plan sets the state's method with respect to how the state Medicaid program will be operated consistent with the federal statutes and regulations in order for the state to qualify for federal financial participation payments. The Secretary of HHS must review and approve each state's plan.

B. Medicaid Drug Rebate Program

88. The Medicaid Drug Rebate Program was established by Congress with the passage of the Omnibus Reconciliation Act of 1990 (OBRA '90). This drug rebate program began operation January 1, 1991. Congress enacted the OBRA '90 Medicaid Drug Rebate Program because "States were not able to address the primary cause of escalating program costs—steep increases in drug prices at the product level—because drug manufacturers would not negotiate lower prices with Medicaid programs."[12]

89. The Medicaid drug rebate program was to enable the states to address manufacturer drug prices. Legislative staff involved with development of OBRA '90 have stated that Congress designed the Medicaid Drug Rebate Program "to offer Medicaid the prices that they (drug manufacturers) were giving to their best customers, or their "best price.""[13] In other words, this legislation was intended to provide the governmental drug program with the economic benefit of market-based prices similar to those available to the best non-governmental drug purchasers. Congress also expected the Medicaid Drug Rebate Program to allow "expansion of Medicaid benefits . . . being constrained by budget limits on federal and state spending for social programs."[14]

[12] Pollard, Michael R. and Coster, John M., "Update I. Legislation. Savings for Medicaid Drug Spending," *Health Affairs*, Summer 1991, pp. 196-206.
[13] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[14] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.

90. By reducing the net drug expenditures of the state, the advent of the Medicaid Drug Rebate Program in 1991 enabled states to extend coverage to a larger population and to expand the number of prescriptions dispensed. State Medicaid programs have enlarged the number of beneficiaries and thus increased access to prescription drugs through this government financed and subsidized program. This government drug program has provided access to prescription drugs for many people who could not have afforded their drugs before, thus increasing total sales for drug manufacturers.

91. Drug firms must voluntarily agree to participate in the Medicaid Drug Rebate Program in order to have their drug products covered by the Medicaid program. For those who voluntarily participate in the drug rebate program, reporting of their drug product prices (i.e., AMP and best price) is required. Manufacturers chose to participate in the drug rebate program and to report the required price information in order to have their drug products covered by the state Medicaid programs, because otherwise they realized that they would lose a substantial amount of sales. The average manufacturer price (AMP) is based on the weighted average of the aggregate sales revenue received by the manufacturer and divided by the aggregate units sold.

92. Because the Medicaid drug program paid for approximately 10% to 15% of outpatient drug purchases in this country, the failure of a manufacturer to participate in the Medicaid Drug Rebate Program would likely have affected the purchasing decisions of pharmacies. For most generic drug products, a pharmacy typically likes to purchase only one manufacturer's drug product and if that drug manufacturer does not participate in Medicaid, the pharmacy would have to stock a second manufacturer's drug product. Instead, the pharmacy would only purchase generic drug products from manufacturers

that were participating in the Medicaid drug rebate program to avoid having a duplicate inventory and the increased inventory carrying cost.

93. The Secretary of HHS has authority to terminate manufacturers and their drug products from coverage in Medicaid if the manufacturer fails to participate in the Medicaid Drug Rebate Program (Social Security Act, § 1927(b)(4)(B)). The rebate agreement obligates the drug manufacturer to report to CMS its AMP and, if applicable, its best price for each drug product (by NDC number) on a quarterly (i.e., four times a year) basis. State Medicaid programs then have to report to CMS, and each participating drug manufacturer, the quantity of each drug product (by NDC) paid for by the state's Medicaid program in a given quarter. This unit volume is multiplied by the Unit Rebate Amount (URA) provided by CMS to the states to calculate the amount of rebate due based on the rebate formulae specified in federal statute.

94. Simplistically, drug firms selling single source (patented brand) drug products or innovator multiple source (off-patent brand) drug products must pay a rebate which is the greater of: (1) 15.1 percent of the AMP; or (2) the AMP less the best price offered to certain classes of trade. In addition, an inflation adjustment rebate factor is also due. Non-innovator multiple source (off-patent generic or non-originator brand) drug products pay a fixed percentage rebate of 11% of AMP. These generic drug products are not subject to either the best price calculation or the inflation adjustment rebate.[15]

95. If manufacturers report inflated prices (AWP, WAC or DP) used for Medicaid reimbursement, the amount of rebate received by the Medicaid Drug Rebate Program does not, in fact, result in Medicaid programs receiving manufacturer rebates that reduce

[15] National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs, 2007*, pp. 4-24.

the ultimate drug cost to a point equivalent to the cost of the manufacturers' best non-governmental customers.

96. The Defendants incorrectly argue that "knowing full well that it was paying a "spread" to providers, California pursued supplemental rebates from drug companies to defray the costs of Medi-Cal drug coverage." [Defendants' Memorandum of Law In Support of Its Motion to Dismiss, Filed January 17, 2006, p. 11.] As noted earlier, the Medicaid Drug Rebate Program, including both federal and state rebates, was intended to enable states to address "the primary cause of escalating program costs—steep increases in drug prices at the (drug manufacturer) product level."[16] This drug rebate program was not intended to compensate for pharmacy reimbursement under Medicaid "[b]ecause states had made pharmacy reimbursement a primary focus of their Medicaid drug program cost containment efforts in the 1980s."[17] For this reason, the rebate program was designed to be entirely separate from the pharmacy reimbursement program and to prevent Medicaid programs from further cutting pharmacy reimbursement. In fact, "Congress sought to limit cuts in this area by seeking a freeze on state pharmacy reimbursements."[18]

C. Role of AMP in Medicaid Drug Program

97. Various defendants in the AWP cases have suggested that availability of AMP information to the government impacts the potential liability of defendants for reporting highly inflated AWPs.

98. This position by the defendants is inconsistent with Medicaid statutes, regulations, policies, and practices. First, the statutes did not allow any other use of the AMP and

[16] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[17] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[18] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.

best price data other than calculation of the unit rebate amounts under the Medicaid drug rebate program. Second, the unit rebate amounts provided to the states by CMS under the drug rebate program cannot usually, or reliably, be reverse engineered to determine the AMP. Third, even if the statute did not prohibit disclosure or use of AMP, or if determination of the AMP could be reverse engineered by the states, the use of AMP as a basis for reimbursement is not practical for other reasons.

99. First, the statutes did not allow any other use of the data other than calculation of the unit rebate amounts under the Medicaid drug rebate program. Until recently, when the Deficit Reduction Act of 2005 (DRA) was passed, the Medicaid rebate statute which defines AMP and its use specified that the AMP information provided by manufacturers "shall not be disclosed by the secretary...or a State agency...except as the secretary determines to be necessary to carry out this section." [42 U.S.C. § 1396r-8(b)(3)(D)]. As a result of this statute the Secretary did not give the states the AMP data for specific prescription drugs. [*See* Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442, 48475 (Sept. 19, 1995) (preface to the proposed rule in 1995 expressly discussing Secretary's limitation on access to AMP data by the states)]. In a hearing before Congress, the Secretary of HHS publicly expressed the view that HHS was not permitted to use the AMP data for Medicare reimbursement. [*See* "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. On Health Care of the S. Finance Comm., March 14, 2002, Statement of Thomas A. Scully, 2002 WL 399357].

100. One state (i.e., Texas) specifically requested clarification from CMS as to whether or not states could use rebate program information to calculate an estimated acquisition cost (EAC) for (pharmacy) reimbursement.[19] The reply from CMS clearly re-stated the issue as: "First, you ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for (pharmacy) reimbursement."[20] The CMS answer was also clear and direct: "You are correct."[21]

101. California Medi-Cal personnel had the same understanding as that stated by CMS in its letter to Texas. [See Deposition of Craig Miller, Medi-Cal Rebate Section]. According to Kevin Gorospe of Medi-Cal all URA information is held confidential and the state realizes that if it were to utilize the rebate information for reimbursement, such a use would breach the confidentiality restrictions. [Deposition of J. Kevin Gorospe, *California v. Abbott Laboratories*, December 3, 2008, pp. 286-287].

102. Personnel from various other state Medicaid agencies have also testified that they were well aware that the Medicaid rebate information (i.e., URAs and AMPs) was confidential and could not be used for reimbursement purposes. For example, Ms. Farrand, the New Hampshire Department of Health and Human Services designee, clearly understood that the URA data provided to states was not to be used for reimbursement purposes and that the data was confidential and not to be disclosed. [Deposition of Lise Farrand, Pharmaceutical Services Specialist, State of New

[19] Letter from Patrick J. O'Connell, Assistant Attorney General, Office of the Attorney General, State of Texas to Mr. Dennis Smith, Director, Center for Medicaid State Operations, CMS, re: Request for Information from State of Texas, dated March 31, 2003.
[20] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.
[21] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.

Hampshire, Department of Health and Human Services, deposed in *U.S. ex rel. Ven-A-Care v. Dey et al*., October 28, 2008, pp. 226, 287-293; see also Deposition of Margaret Clifford, Pharmaceutical Services Specialist, State of New Hampshire, Department of Health and Human Services, served from 1994 through 2000, *U.S. ex rel. Ven-A-Care v. Dey et al*., October 29, 2008, pp. 196-230]. The Medicaid agency designee for the State of Washington also understood that the URAs provided to the state by CMS were not to be disclosed and were not to be used as the basis for reimbursement. [e.g., see Deposition of Ayuni Hautea-Wimpee, *U.S. ex rel. Ven-A-Care v. Abbott Laboratories et al*., November 24, 2008, pp. 594, 606-608]. The Director of the Department of Human Services, State of Hawaii, in a State Plan Amendment memo to HCFA noted, "The State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." [Letter from Winona E. Rubin, Director, Department of Human Services, State of Hawaii, Re: State Plan Amendment # 92-08, to Mr. Lawrence L. McDonough, Associate Regional Administrator, Health Care Financing Administration, San Francisco, CA, May 13, 1992; see also, Deposition of James Parker (IL), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Nov. 18, 2008, pp. 72-74; and Deposition of Suzette Bridges (AR), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 10, 2008, pp. 70-72].

103. Second, the URA provided to the states under the drug rebate program cannot be reverse engineered to determine the AMP. The primary functions of the Medicaid Drug Rebate Program are carried out by CMS at the federal level. This federal rebate operation includes receiving the AMP and best price information from participating drug manufacturers, application of the inflation adjustment factor, and

calculating a single value (URA) for each drug product for each quarter. This URA is the value provided quarterly to state Medicaid programs to multiply by their quarterly drug utilization volume to determine the rebate amount due from a drug manufacturer. The state's role in the Medicaid Drug Rebate Program is to track the state's drug utilization, to bill the drug manufacturer for rebates, and to resolve any disputes over rebate amount that result from discrepancies in drug utilization.

104. Consistent with the statute, and related regulations and Medicaid Drug Rebate Program implementation procedures, the Secretary has not provided the state Medicaid programs with AMP values over time. The states were provided URAs and not AMPs. [60 Fed. Reg. 48442, 48475 (Sept. 19, 1995) (preface to proposed rule in 1995) (expressly discussing Secretary's limitation on access to AMP data by the states).

105. The URAs included the total amount per unit (e.g., tablet, capsule, or milliliter) due to Medicaid based on provisions of the rebate program including: the minimum rebate amount (i.e., AMP – 15.1%) and, if applicable, the best price rebate amount (AMP – best price), and the inflation adjustment amount. Because this URA incorporates multiple factors in a single number, including the minimum rebate amount, the best price rebate amount, and the inflation adjustment factor, it is not possible, on a reliable and consistent basis, for states to disaggregate the single number reported as a URA into the contribution made by each of the components. [*See* the CMS document titled "Unit Rebate Amount (URA) Calculation" found on May 15, 2008 at: http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/uracalc.pdf]. The URA is the only number provided to state Medicaid programs prior to the Deficit Reduction Act of 2005. With the passage of the DRA in 2005, Congress authorized

provision of the AMP amounts for all covered drug products to states beginning in 2007. [DRA, Pub. Law 109-171 § 6001, 120 Stat. 4, 54 (2006)].

106. The URA for multisource non-innovator drug products was 11 percent of the AMP. While this single factor in the URA for a specific drug product could arguably, in some cases, signal the AMP amount to states, this reverse engineering of the AMP was not permitted, as noted earlier, for any purpose other than collection of Medicaid rebates.[22] Furthermore, the AMP submitted to the Medicaid Drug Rebate Program by drug manufacturers is provided based on the 9-digit NDC code and not the 11-digit NDC code. Therefore, the AMP for an individual drug product at the 11-digit NDC code level cannot be reliably determined by reverse engineering AMP data provided at the 9-digit NDC level. Given the precision that states need to have in order to set reimbursement rates, this is not a reliable process to determine the payment amount for thousands of generic (multiple source) drug products.

107. Recall that every prescription drug product in the United States has a unique NDC number (11-digits) for each drug product marketed. This 11-digit number has three basic segments. The first segment (5-digits) uniquely identifies the drug firm and the second segment (4-digits) identifies the specific strength, dosage form, and formulation for a given drug product. The third segment (2-digits) identifies the package size and package type (e.g., bulk, unit dose, or unit of use). While products with the same 9-digit code are the same drug entity, dosage form, strength and manufacturer, there may be varying package sizes (e.g., 30 tablets v. 100 tablets v. 5,000 tablets) and varying package types (e.g., bulk bottle v. unit dose). The price of different package sizes and

[22] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.

types may vary a little or a lot depending upon the drug firm, the drug product and the types of pharmacies or providers to which the drug manufacturer will sell each specific NDC or package type.

108. CMS has always asked drug manufacturers to report their AMP data at the 9-digit level based on the weighted average AMP across all related 11-digit NDCs. As noted by CMS in the Federal Register: "We agree that the AMP should continue to be weighted at the 9-digit NDC level, and retain this requirement in the final rule. CMS has used the weighted 9-digit AMP since the start of the rebate program and there is nothing in the statute or legislative history to indicate that the Congress meant for this to change when AMP is used for FULs."[23]

109. Just knowing the URA for a drug product does not mean that one knows the price that any given pharmacy paid or how many pharmacies could buy the drug product at or below that amount. The URA does not mean that one knows the underlying distribution of prices that made up that average manufacturer price. [e.g., see Jerry Wells, State of Florida, December 15, 2008, deposition in *U.S. ex rel. Ven-A-Care v. Abbott*, p. 260.]

110. Third, even if the statute did not prohibit disclosure or use of AMP, or if determination of the AMP could be reverse engineered by the states, the use of AMP as a basis for estimated acquisition cost (EAC) or other reimbursement purposes was not practical for reasons which include the following: (1) AMP was not publicly available so that pharmacies and other providers would not know the amount they would be paid for providing prescription drugs; (2) use of AMP-based reimbursement would have required

[23] See CMS, Medicaid Program; Prescription Drugs, Final Rule, *Fed. Reg*., July 17, 2007, p. 39215.

a complete change of the entire Medicaid drug program's pharmacy reimbursement system and not just a minor adjustment to the existing system; and the manufacturer-reported AMP amounts are subject to change after they have been reported and can be revised years after they have been initially supplied to CMS. [See Deposition of Craig Miller, Medi-Cal, October 22, 2008, pp. 328-329.]

111. Pharmacies agree to provide prescription drugs to beneficiaries of state Medicaid programs based on a contract, and/or pricing information, that is available to the pharmacy prior to dispensing the prescription. If AMP were used for estimating acquisition cost (EAC) for reimbursement purposes—a use which was not permissible—the confidential nature of AMP would have created an uncertain business proposition for the pharmacies. Essentially, the pharmacies would be faced with a proposition from Medicaid which says, "if you agree to participate in the Medicaid program you will be paid the lower of an estimated acquisition cost based on AMP—a price which we cannot disclose to you—plus a dispensing fee, a federal upper limit (or maximum allowable cost, MAC) based on AMP plus a dispensing fee, or your usual and customary price to the general public." A pharmacy business is not likely to agree to provide prescriptions to Medicaid when they do not know the amount that will be reimbursed for the prescription until after the prescription has already been dispensed. This is not a reasonable business arrangement for the pharmacy.

112. Finally, the adoption and implementation of an AMP-based reimbursement system to pay pharmacies for prescriptions under Medicaid is not a simple administrative change. Instead, this shift would have required a complete change of the entire Medicaid drug program's pharmacy reimbursement system and not just a minor

adjustment to the existing system. In fact, sometime after the relevant time period in this action, Congress passed the DRA to require, *inter alia*, a major change in the reimbursement system using AMP as a basis for setting federal upper limits for generic drugs. CMS published proposed rules and later final rules for implementing an AMP-based reimbursement system that would also have disclosed AMP prices to the public. For a variety of reasons, the CMS final rule and the process by which it was promulgated were considered problematic by the community pharmacies. These pharmacy groups filed a motion for preliminary injunction to halt the execution of the AMP-based FUL reimbursement and the posting of those prices for the public.[24] The federal court granted this preliminary injunction in December of 2007.

D. Prescription Reimbursement Under the State Medicaid Drug Programs

113. State Medicaid drug programs pay for prescription drugs provided to Medicaid enrollees through community pharmacies based on a method known as a 'lower of' formula. That formula, as described in the Medicaid regulations, and also routinely reported in the NPC Medicaid Book [NPC, *Pharmaceutical Benefits*, 1993, p. 15., and other annual volumes] states drug reimbursement or payment "is not to exceed the lowest of:"

- the maximum allowable cost (MAC) of the drug as established by HCFA's [now CMS's] pharmaceutical reimbursement board for certain multisource drugs (generic drugs), plus a reasonable dispensing fee;
- the estimated acquisition cost (EAC) of the drug (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers), as determined by the program agency, plus a reasonable dispensing fee; or
- the providers' usual and customary charge to the public for the drug.

[24] I have provided an expert report on behalf of Plaintiffs on November 13, 2007 in *National Association of Chain Drug Stores and National Community Pharmacists Association v. U.S. Department of Health and Human Services and Michael O. Leavitt, Secretary of HHS, and CMS, and Kerry Weems, Acting Administrator of CMS*, U.S. District Court for the District of Columbia, Case No. 1:07-cv-02017.

114. CMS (formerly HCFA) regulations clearly state that the estimated acquisition cost is meant to be "as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)" as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14]. The state Medicaid programs are expected by CMS to meet this objective.

115. As noted earlier, this description of EAC emphasizing that this term is supposed to represent a price that is "as close as feasible to the price generally and currently paid by the provider" or a similar statement has been reported in every annual volume of the NPC Medicaid Book from 1979 to 2005-2006. Sandoz was aware of, and had access to, this publication since Sandoz has been a sponsoring member of the National Pharmaceutical Council since 1983 or before.

116. The state Medicaid approach to estimating acquisition cost—their best estimate of actual acquisition cost—relies upon data reported by manufacturers, pharmacies and other providers. As noted previously, the state Medicaid programs rely upon drug pricing information from drug manufacturers provided through a commercial drug price database, including AWP, WAC, and DP. The vast majority of state Medicaid programs rely primarily upon the AWP. The state Medicaid drug programs then use this information in a formula that determines the 'lower of': (1) the estimated acquisition cost, calculated based upon the price representations of drug manufacturers, plus the

dispensing fee, (2) the MAC or FUL amount plus a dispensing fee, or (3) the pharmacy's usual and customary charge for the prescription as reported by the pharmacy.

117. Additionally, the total amount of payment to pharmacies and providers for a prescription must be taken into account, including both the drug product cost payment and the dispensing fee payment. As noted in a research report to CMS [Wrobel, Schondelmeyer, et al., *Case Study of the Texas Vendor Drug Program,* 2005, p.67]:

> Stakeholders also agreed that, if the public sector did seek to improve the accuracy of its estimates of acquisition costs for use in Medicaid payment, then it would be absolutely essential to improve the accuracy of estimates of the cost of dispensing. Although many stakeholders acknowledged that current estimates of acquisition costs and the resulting drug product payment levels might be inflated, they also believed that current estimates of dispensing costs and Medicaid dispensing fees were too low. The combined effect of the two components of estimated cost (the drug product cost and the dispensing fee) is what ultimately determines payment and the financial performance of the retail pharmacy.

While the payer, Medicaid, may take into account a known drug product spread amount (such as the AWP to WAC spread) when establishing the reimbursement formula including the pharmacy dispensing fee or physician administrative fee, it is contrary to public policy for the amount of a spread to be hidden from the payer (i.e., the state Medicaid program) or to be manipulated by the drug manufacturer. For example, Stanley Rosenstein of Medi-Cal explained "we spent all day talking about the effort we've had to get accurate pricing. Had we started with accurate pricing, we wouldn't have had to go through all of these changes, and we would have had an accurate reimbursement system in the Medi-Cal program. That would have saved the taxpayers hundreds of millions of dollars." [Deposition of Stanley Rosenstein, November 6, 2008, p. 304.] Additionally, the Colorado Medicaid agency designee stated that he was not "aware of any policy or practice of Colorado Medicaid to pay excessive reimbursement to cover any claimed inadequate dispensing fee." (Deposition of Allen D. Chapman, *U.S. ex rel. Ven-A-Care*

v. Dey et al., December 15, 2008, p. 331.) In addition, this Colorado Medicaid representative testified that he was aware of no information that "Colorado approved of drug companies incentivizing pharmacies based on Medicaid reimbursement." (Deposition of Allen D. Chapman, State of Colorado, *U.S. ex rel. Ven-A-Care v. Dey et al.*, December 15, 2008, p. 343.)

118. The setting of payments for prescription drugs is also critical to providing access to prescriptions and pharmaceutical care. For example, the Medicaid program wants to ensure that enough pharmacy providers choose to participate so that patients will have access to the drug products they are prescribed within a reasonable distance from the patient's home or work.

119. Consequently, it is critical for the Medicaid system to have an accurate estimation of the cost of dispensing, as well as the amount that a pharmacy paid to acquire a drug product, so that the reimbursement can be set at the proper level. Every Medicaid program, and the federal Medicare program, has structured its reimbursement with separate components for dispensing (or administrative) fees and drug product (ingredient) cost reimbursement in order to permit the highest degree of control for the programs over each of those components. Plainly, however, even if a Medicaid program were to determine that it would be advantageous to set below-cost dispensing fees, and "make up" for the shortage by paying higher drug ingredient cost reimbursement, it would nonetheless be critical for the program to have accurate and reliable cost information in order to strike the proper balance that the program deemed appropriate and to ensure that any reimbursement decisions were meeting the Medicaid program's objectives. [e.g., see Deposition of Ayuni Hautea-Wimpee (WA), *U.S. ex rel. Ven-a-Care*

v. Abbott Lab, Inc., 06-11337-PBS, Nov. 24, 2008, p. 148; Deposition of Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 241-244; and Deposition of Allen Dale Chapman (CO), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 2008, pp. 323-324.]

120. I have been asked to address the following assertions by Defendants:

> In sum, like so many other states, California has long known that it reimbursed providers substantially more than what the providers paid to acquire Defendants' drugs. And, like other states, California did so as a result of political factors or to insure adequate provider participation in Medi-Cal.
>
> (Defendants Memorandum of Law In Support of Its Motion to Dismiss, Filed January 17, 2006, p. 11.)

These assertions by Defendants are not consistent with, and are in direct opposition to, long standing Medicaid statutes, regulations, policies and practices. The following paragraphs in this section, and throughout my report, describe and explain how these assertions are not supported.

121. As noted elsewhere in this report, the Medicaid regulations clearly state that the estimated acquisition cost is meant to be "as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as is possible to actual acquisition cost." [42 CFR Part 447.301; see also Fed Reg, Vol. 52, No. 147, July 31, 1987, pp. 28648-58; and see "HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)" as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14].

122. The Defendants (i.e., Dey, Mylan and Sandoz) knew the purpose of the Medicaid program and the method used to estimate acquisition cost. Instead of reporting prices "as close as feasible to the price generally and currently paid by the provider", however, the Defendants knowingly reported and continued to report prices that were not close to the prices actually paid and even lowered their actual prices while at the same time they held constant, or even raised their reported prices in some cases, to influence the payments to providers and thus the sales of their drug products.

123. Some Medicaid officials did become aware that published AWPs were not the pharmacy's actual acquisition cost. This awareness may have come from Medicaid audits, OIG studies, and GAO studies that selectively examined the relationship of AWP to actual invoice prices paid by pharmacies. The Medi-Cal program understood and expected that there was a known relationship between AWP and WAC (or pharmacy invoice prices), especially for brand drug products, such that an estimated acquisition cost (EAC) could be determined by AWP minus a certain percentage. Medi-Cal did adopt an EAC methodology that was based on the relationship of AWP to WAC (i.e., AWP is 20 to 25 percent above the WAC, or WAC is 16.67 or 20 percent below AWP, previously noted). This difference between the AWP and WAC can be referred to as the AWP-WAC spread or the formulaic spread.

124. When pharmacy actual acquisition prices have been selectively studied, they have sometimes been found to be substantially below the reported prices, and this is especially so for generic or multisource drug products. As described elsewhere in this report, some multisource and generic drug products will have AWPs that are the typical

20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC.

125. Drug manufacturers with multisource or generic drug products usually lower their actual transaction prices due to price competition from other multisource drug products, but their reported prices (AWP and WAC) typically remain the same or even, in some cases, increase. Dey, Mylan and Sandoz have engaged in such pricing conduct as described elsewhere in this report. The spread between AWP and actual prices or between WAC and actual prices is known as the EAC-AAC (actual acquisition cost) spread or, sometimes as the mega-spread because these spreads can be as much as 30 percent to more than 1000 percent above the actual price. In fact, in the relevant time period, the Defendants created and used mega-spreads that ranged from 42% to 8400% for Mylan, 42% to 3600% for Sandoz (Geneva), and 13% to 1837% for Dey for specific drug products initially named by California in this case [see California's First Amended Complaint, *California v. Abbott Labs, et al*., August 25, 2005, Exhibit C, Dey Drug Pricing Information, Exhibit H, Mylan Drug Pricing Information, and Exhibit D, Sandoz Drug Pricing Information.]

126. The state Medicaid programs expected that the manufacturer prices reported to the price databases were based on actual or transaction prices, or based on the known relationship to actual prices. In cases where Medicaid or others conducted an audit of invoices, the auditors expected that the manufacturer and wholesaler prices on invoices to pharmacies were actual prices. Medicaid administrators were not aware that certain manufacturers, such as Dey, Mylan and Sandoz, inflated these prices (AWP, WAC, DP or other prices found on invoices) to increase their sales, to increase

reimbursement to pharmacies, or to distort the expected relationships to actual prices at any point in time or over time.

127. Even if the Medi-Cal program was to have taken into account a known drug product spread amount (such as the AWP to WAC spread) when establishing the pharmacy dispensing fee, it undermines the policy objectives of the Medi-Cal program for the amount of a spread to be hidden from the payer (i.e., the California state Medicaid program) or to be manipulated by the drug manufacturer unbeknownst to the Medi-Cal program. To the extent that a drug product cost spread exists, and is known to Medi-Cal, the Medi-Cal program could have adjusted EACs or dispensing fees, but such a payment policy is the purview of Medi-Cal and not drug manufacturers. In order to be able to make such payment decisions, Medi-Cal assumes, and depends upon, accurate and reliable price information from manufacturers in order to strike the proper balance that the program may deem appropriate and to ensure that any reimbursement decisions meet the Medi-Cal program's objectives. [e.g., see Deposition of Kevin Gorospe (CA), December 3, 2008, *State of California, ex rel Ven-A-Care v. Abbott Laboratories, Inc.*, et al, Case No. 03-CV-11226, pp. 294-6 to 295-18.]

128. Defendants have made various arguments about tradeoffs, or cross-subsidization, related to Medicaid drug payment policy. They have suggested that Medicaid payment policy takes into account tradeoffs between: (1) drug ingredient cost and dispensing fees; (2) drug ingredient costs and a desire to incentivize dispensing of generics; and (3) drug ingredient costs and a desire to incentivize pharmacy participation and beneficiary access.

129. In 1994, HCFA formally stated: "We would also clarify our policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug product." [August 12, 1994, Memorandum from Sally Richardson, Director of HCFA's Medicaid Bureau, To All Associate Regional Administrators (HHC902-0878).] This same message was forwarded to state Medicaid agencies through their regional administrators. To my knowledge HCFA (or CMS) has not withdrawn this policy.

130. From my experience working with Medicaid officials at both the federal and state levels, I understand that Medicaid officials considered the various objectives of the programs when they set reimbursement formulae. If evidence and experience demonstrated that payment adjustments were needed, the Medicaid program officials adapted their methodologies or developed alternative methods to address the concerns. However, to the best of my knowledge, nowhere in the statutes, regulations, rules or policies for Medicaid payment is there authorization, or even a mention, of manufacturers being asked to inflate their drug prices to "help" the programs achieve the tradeoffs that may be necessary to accomplish the programs' objectives.

131. Even if a Medicaid official wanted, rightly or wrongly, to take into account the difference in Medicaid ingredient cost allowance and actual acquisition cost as a trade off to other factors, he or she would not possess the information necessary to make such a tradeoff because Medicaid officials do not know the actual prices or range of prices charged by a manufacturer in the market. To the contrary, the only way for programs to achieve their desired objectives is for them to be given accurate, timely and reliable information about prices.

132. Additionally, to the extent that any state saw a need to pay additional dispensing or administration fees for infusion drugs, such a determination was within the state's policy making discretion, but was not intended to be left to, or even co-opted by manufacturers, based on a system of reporting inflated prices for these drugs. Notably, states that saw a need to pay additional infusion dispensing fees did so as they considered it appropriate and affordable. For example, at some point during the relevant period, at least 9 states have had an increased infusion fee and at least 16 states have paid a higher compounding fee. In addition, at least 16 states pay a higher unit dose (or long term care) dispensing fee.

133. Likewise, to the extent that any state saw a need to pay an additional dispensing fee as an incentive to the pharmacies to dispense generic drug products such a determination was within the state's policy making discretion, but was not intended to be left to, or even co-opted by manufacturers, based on a system of reporting inflated prices for these drugs. Notably, states that saw a need to pay additional generic dispensing fees as an incentive did so as they considered it appropriate and affordable. For example, at least 9 states have paid a higher generic incentive fee at some time during the relevant period.

134. Regardless of whether or not some state Medicaid officials viewed their estimated acquisition cost method within federal guidelines as a tradeoff for, or cross-subsidization of, other factors, the states did not rely upon nor expect the drug manufacturers to set unknown prices with high spreads to cross-subsidize. As a matter of policy, the states would not design a payment system that delegates the amount of payment to providers to be at the discretion of the drug manufacturers. Even if states did,

or desired to, cross-subsidize with other factors, the states would have needed complete, accurate, and timely price information from the drug manufacturers. The drug manufacturers did not provide the state Medicaid programs with complete, accurate, and timely price information and their reporting of inflated prices that were not transparent to the public programs did not serve government policy objectives effectively.

E. Federal Upper Limits (FULs) and Maximum Allowable Costs (MACs)

135. The Medicaid payment formulae include maximum allowable cost provisions. There are two basic types of maximum allowable costs (MACs): (1) federal MACs, also known as federal upper limits (FULs) and (2) state MACs, known in California as Maximum Allowable Ingredient Costs (MAICs). However, not all generic drug products have either a federal or a state MAC.

136. A FUL is set by the federal Medicaid program based upon specific criteria that will trigger whether or not a FUL may be established. Prior to the DRA [Deficit Reduction Act of 2005, Pub. Law 109-171 § 6001, 120 Stat. 4, 54], FULs were established only when three or more 'therapeutically equivalent' drugs (in the same drug product group) were on the market.[25]

137. Not all generic, or off-patent, drug products have federal FULs or state MACs. Prior to the DRA, there were about 500 drug product groups with an established FUL. Under the new rule issued to implement the DRA, the number of drug product groups with FULs was expected to grow to 3,000 or more.[26] Minnesota has State MACs

[25] The term 'therapeutically equivalent drugs' is used in the proposed rules to mean "drugs that are identified as A-rated in the current edition of the FDA's publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (including supplements or successor publications)." See CMS, Medicaid Program; Prescription Drugs, Final Rule, Fed. Reg., July 17, 2007, p. 39154.

[26] Analysis of data on FULs, state MACs, commercial MACs, and other pricing data provided through personal communication with George Saunders, Pharm.D., Vice President, Professional Services,

or FULs for 734 drug product groups and Washington has about 1,400 drug product groups with State MACs or FULs.[27]

138. Even today, when states have become more aggressive with MACs, state-negotiated rebates, and other forms of cost containment, a large proportion of the generic drug products do not have MACs or FULs. To illustrate the relative proportion of multisource products with and without MACs (or FULs), actual data from Medi-Cal was examined for 2006. The number of prescriptions and the amount of drug expenditures for the Medi-Cal drug program were categorized by their patent status and by the presence or absence of an FUL. Single source brand name drug products were 27.5 percent of the prescriptions, but accounted for 66.6 percent of the drug program expenditures. Nearly three-fourths (72.4 percent) of the prescriptions were for multisource drug products and one-half of those multisource drug products had FULs while the other one-half did not. Expenditures for multisource generic drugs without FULs represented 21 percent of the total drug expenditures, and multisource generic drugs with FULs represented 12.4 percent of total drug expenditures.[28]

139. Some generic drug products were subject to a FUL, or a state MAIC, at some point in time. Even for these generic drug products, the reimbursement for such generic prescriptions may still have been influenced by the manufacturer's reporting of inflated prices. If the drug manufacturer had reported a price generally or currently paid

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AmeriSourceBergen, e-mail on June 28, 2006 and an excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

[27] Minnesota Medicaid has 734 drug product groups with State MACs which includes the 496 drug product groups with federal FULs. The number of State MACs in Minnesota compared to other states ranks 24th with the largest number of State MACs being nearly 1,400 in Washington. See George Saunders, AmeriSourceBergen, e-mail on June 28, 2006 and excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

[28] Myers & Stauffer, *Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California*, December 2007, pp. 36 and Table 4.1.

as the AWP, in some cases, the AWP may have resulted in an ingredient amount that was lower than the FUL limit for the generic product. In this case, the reporting of an accurate AWP would have resulted in Medi-Cal reimbursing a lower amount for such generic prescriptions. Additionally, reporting of a transaction-based AWP or WAC might well have changed the FUL that was set, affecting reimbursement for all prescriptions (i.e., all manufacturers versions of the generic drug product covered by the FUL) reimbursed under that FUL.

F. Role of Commercial Drug Price Databases

140. Drug information and price databases serve an essential role in the pharmaceutical marketplace. These databases facilitate, *inter alia*: (1) the identification and processing of prescription claims, (2) the screening for drug-drug, drug-disease, and drug-food interactions, (3) access to other safety and clinical information related to drug products, (4) pricing and payment for prescription drugs, and (5) determination of drugs available on the market and whether FDA-approved generics are available.

141. The role of these drug price databases was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 21-22] as follows:

> Three commercially available drug price databases track list prices of drug products in the U.S. market at the AWP and WAC levels. These databases are: (1) the Blue Book (First DataBank, Hearst Publishing Co., Palo Alto, CA); (2) MediSpan Master Drug Data Base and PriceChek PC (Facts & Comparisons, Wolters Kluwer Health, Inc., Indianapolis, IN); and (3) the Red Book (Thomson-Medical Economics, Montvale, NJ). Historically, each of these firms published a price list in printed format once a year with quarterly updates. Since the mid-1980s, however, the electronic version of these databases has been the primary format for price list publication. These databases are updated on a continuous (daily) basis. In addition to price data, these databases also contain or link to other databases that provide descriptive and clinical information on drug products including therapeutic class and uses, drug interactions, patent and regulatory status, therapeutic equivalence and generic alternatives, and many other useful data elements.

> The principal users of these drug price databases are pharmacies and third party programs. Pharmacies use the drug price and clinical information database on their in-store computers for pricing, filling prescriptions, drug interaction screening, and submission of third party prescription claims. Third party payers (public and private) use these databases to screen, adjudicate, and determine payment for covered prescriptions. Virtually every third party program (public or private), or its claims processor, use one of these drug price databases as the source for AWP, or WAC, values that serve as the basis for calculating the price that a pharmacy will be paid for each drug product based on the NDC number. This price information is then used according to the contractual pricing formula to pay the pharmacy for the prescriptions dispensed to eligible recipients. The vast majority (more than 40) of the state Medicaid programs use First DataBank's drug price information as the basis for prescription drug payments to pharmacists and other providers.

142. The various players in the pharmaceutical market (i.e., drug manufacturers, drug wholesalers, pharmacies, providers, and third party payers), including Dey, Mylan, and Sandoz, recognized the role of drug price databases in the payment and reimbursement for prescriptions under third party programs including the state Medicaid programs.

143. Furthermore, these players in the pharmaceutical market, including the drug manufacturers and specifically Dey, Mylan, and Sandoz understand that the various types of price data reported by drug manufacturers, either directly or indirectly, to the drug price databases will result in setting the AWP, WAC, and/or DP for each specific drug product at the NDC (national drug code) level at any point in time.

144. Medi-Cal pays for millions of pharmaceuticals claims each year and attempts to do so in a manner that will maximize the medical services and products that can be provided to beneficiaries based on the funds available to the program.

145. Government policy makers and implementers with responsibility for large healthcare reimbursement programs (e.g., Medicare and Medicaid) need to rely upon readily available and current market information such as that supplied by drug

manufacturers and drug price publishing services because of the large number of claims that make individual transaction prices impractical and inefficient to determine on a claim by claim basis. (e.g., see Deposition of Stan Rosenstein, *California ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 03-CV-11226-PBS, November 6, 2008, pp. 300-302; Deposition of Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 241-242; Deposition of Allen D. Chapman, State of Colorado, *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 15, 2008, pp. 323-324.)

146. Pharmaceutical pricing conduct, in part, includes the setting of prices by drug manufacturers and the reporting of drug prices to commercial drug price publishers and to state and federal pharmaceutical reimbursement programs such as Medicaid and Medicare.

147. Most state Medicaid programs, including Medi-Cal, rely on drug price and cost information published by price publishing services such as Hearst Corporation's First DataBank—also known as Blue Book. The prices published by price publishing services such as First DataBank's Blue Book or Thompson Publishing's Red Book were based upon price data reported by the drug's manufacturer.

148. Drug manufacturers knew that the state Medicaid drug programs relied upon First DataBank for the AWP and/or WAC prices used in Medicaid payment formulae. In First DataBank's own newsletter, it reported that: "We deliver our prices to 43 of the state Medicaid programs, all of the major drug wholesalers, third party payors and pharmacies all across the country." Also, drug manufacturers knew that the AWP and WAC prices reported by First DataBank were represented by First DataBank as follows: "Since AWP is the Standard in the industry you naturally want to use the most

widespread AWP there is. First DataBank has that standard." ["National Drug Data File (NDDF), The Most Comprehensive Drug Database," First DataBank, *Monthly Interest*, March 1993, Vol. 8, No. 3, p.1.]

149. First DataBank over more than a decade [1991 to 2002] has described AWP and WAC as list and benchmark prices that are "prices charged" or the "price at which a particular drug is sold." [See First DataBank, *Monthly Interest*, September 1991; and Letter from Robert Hawley, Office of General Counsel, Hearst Publishing, to Michael Lembke of Alpha Therapeutic Corporation, May 30, 2002.] These descriptions by First DataBank, when taken at the plain meaning of the language used, indicated prices actually "charged" or "price at which the drug was sold." In 2000, First DataBank addressed the question: "What is AWP?" The response reported: "AWP (Average Wholesale Price) is an industry term that represents a benchmark wholesale price a wholesaler would charge a pharmacy for a particular product." ["Medicaid Reimbursement Pricing Issues," First DataBank, *Monthly Interest*, July, August 2000, Vol. 15, No. 6, p.1-3.]

150. The terms, list price and benchmark price, as used by First DataBank and even in my reports and testimony, are not meaningless prices and can not be anything that the manufacturer wants them to be especially when those prices are being reported to the drug pricing compendia for reimbursement purposes. In fact, as noted above, First DataBank refers to the benchmark price as an industry term that "represents a benchmark wholesale price a wholesaler would charge a pharmacy for a particular product." ["Medicaid Reimbursement Pricing Issues," First DataBank, *Monthly Interest*, July, August 2000, Vol. 15, No. 6, p.1-3.] Third party programs use benchmark prices from

the drug pricing compendia (i.e., First DataBank) as a primary component of their reimbursement systems.

151. Having manufacturers report prices that bear no set, or established, or predictable relationship to prices actually charged would obviously not allow a rational judgment to be made about the amount of reimbursement and would result in some prescription payments providing excessive profit to the provider while other prescription payments may not be adequate to cover all real costs. From the policy perspective of the Medicaid program, such an impact would be inconsistent across drug products, subject to the whims and financial benefit of the drug manufacturers or providers, and would encourage the tainting of professional judgment of physicians and pharmacists by profit incentives that are beyond the government's knowledge or control. From the perspective of establishing reimbursement policies so as to incentivize pharmacists or providers to dispense lower-cost generics rather than higher-cost brands, for example, it is extremely important that the system has available accurate, timely and comprehensive price information.[29] If reported prices do not meet these criteria, the program cannot evaluate whether it is in fact incentivizing providers to dispense generics, or whether any such incentive is in an amount that the program deems appropriate.

152. To the best of my knowledge and experience from working with Medicaid drug programs, there is no policy objective within Medicaid that relies upon, or is furthered by, pharmaceutical manufacturers reporting prices that bear no rational or predictable relationship to the prices actually charged in the marketplace. (e.g., see Deposition of Kevin Gorospe (CA), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-

[29] Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, p. 28.

11337-PBS, Dec. 3, 2008, p. 300; deposition of Roxanne Homar (WY), *U.S. ex rel. Ven-A-Care v. Abbott Lab., Inc.*, December 3, 2008, p. 438-439; and deposition of Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 273-276.) To the contrary, Medicaid and Medi-Cal currently and historically have relied upon manufacturers' reporting of prices that do reflect the "prices generally and currently paid by providers" in the marketplace.

153. The Medicaid drug program has had a consistently stated objective for its payment policy to be based on "estimated acquisition cost" (EAC). Drug manufacturers were well aware of this intent with respect to the drug product payment under Medicaid since as far back as 1977. The intent of the Medicaid program regarding drug product reimbursement is "to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider." Drug manufacturers were also on notice that Medicaid's expectation was that: "The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14.] Medi-Cal at all times operated under the same expectations and had statutes, regulations, and other communications that clearly communicated these requirements.

154. I am aware of no regulation, or payer such as Medicaid, that requests, authorizes, or encourages a drug manufacturer to set and report a list price or benchmark price to the drug price compendia as an AWP or WAC that has no relationship to the

prices actually charged in the market. In fact, First DataBank and Medicaid programs, including Medi-Cal, make it clear that the AWPs and WACs reported are used for Medicaid reimbursement and that Medicaid expected that reimbursement would be "as close as feasible to prices generally and currently paid by the provider."

155. The prices reported by drug manufacturers to drug price compendia have traditionally had a predictable relationship to actual market prices generally and currently paid by pharmacies in the marketplace, except for instances where a manufacturer for its own reasons chose to report prices with inflated relationships when compared to the actual prices that are generally and currently paid by pharmacies in the marketplace. This behavior of certain drug manufacturers has resulted in reported prices, such as AWP, WAC, and DP, and their relationship to actual prices generally and currently paid by pharmacies in the marketplace, becoming inflated progressively over time.

156. Drug manufacturers, including Dey, Mylan and Sandoz were aware that state Medicaid programs intended to use the manufacturer reported prices to commercial price databases to estimate the prices "generally and currently paid by pharmacies" in the marketplace. This general intent of state Medicaid programs was published routinely in the annual volumes of the National Pharmaceutical Council's publication "Pharmaceutical Benefits Under State Medical Assistance Programs" (also referred to as the "NPC Medicaid Book"), and other places. Sandoz (either directly or through Novartis) has been a member of the National Pharmaceutical Council throughout the entire period at issue in this case.

G. Dey's Price Reporting Conduct and Impact on Medi-Cal

157. There is evidence indicating that Dey's employees understood and monitored how the drug prices (e.g., AWP and WAC) they published through databases (e.g., First DataBank) would be used and relied upon by others. Dey knew that its reported price information would be used in a formulaic process to set the payment to pharmacies and other providers for dispensing each specific prescription for a drug product at the NDC level to a patient in a given third party program, including state Medicaid programs. Evidence also indicates Dey knew that pharmacies were interested in these published drug prices for drug reimbursement purposes.

158. Dey used pricing strategies that set and maintained high AWPs and, at the same time, created a large spread between the actual selling prices and the amounts that would be paid by third party programs, including Medicare and Medicaid. In a memo describing that "this pricing strategy will be followed by Dey sales people," the objectives of the albuterol pricing strategy included the following: "TO SEEK THE HIGHEST PRICES POSSIBLE IN RETAIL, HOMECARE AND HOSPITAL SEGMENTS." "TO MAXIMIZE DEY PROFITABILITY" and "TO PROVIDE INCENTIVE TO RETAIL / CHAIN PROVIDERS TO USE DEY'S ALBUTEROL UD BY INCREASING THE SPREAD ON MEDICARE / MEDICAID REIMBURSEMENTS." (Memo from Robert F. Mozak, Dey, to Pam Marrs, *et al.* , Dey, RE: Albuterol Pricing Strategies, dated February 24, 1992, DL-TX-0090851). These same three objectives, *inter alia*, were reiterated for a different drug product (Cromolyn Sodium Nebulizer Solution 20mg/2ml) two years later in 1994. (CROMOLYN SODIUM NEBULIZER SOLUTION 20mg/2ml ABRIDGED MARKETING PLAN,

prepared by Robert Ellis, January 1, 1994, DL-TX-0090967-1005, see particularly, DL-TX-0091002.)

159. Dey marketing executives knew how reimbursement for government programs (i.e., Medicare and Medi-Cal) worked, the role of increased spreads or "margins," and that they were selling drug products (i.e., Cromolyn Sodium Nebulizer Solution 20mg/2ml) substantially below the reimbursement rate. The basis for this finding comes from the Marketing Plan for Cromolyn Sodium Nebulizer Solution 20mg/2ml (December 15, 1993). (CROMOLYN SODIUM NEBULIZER SOLUTION 20mg/2ml MARKETING PLAN, prepared by Robert Ellis, December 15, 1993, DL-TX-0091006-1005, see particularly, DL-TX-0091008, -1031, -1056.) The Introduction to the marketing plan explains, "Homecare Pharmacies work in conjunction with DME dealers and Medicare reimbursement…However, lower priced generic cromolyn from Dey will increase the margins and help to mature this distribution channel into larger sales volume." (DL-TX-0091008.) A later section of the Cromolyn Marketing Plan provides projected sales revenues for the Homecare Pharmacy Market. These sales projections are based on a Dey "estimated selling price" for cromolyn of $0.45/unit in 1994 and $0.40/unit in 1995 while at the same time the HCFA (Medicare) reimbursement rate is footnoted to have been $0.74 per unit of cromolyn. (DL-TX-0091031.) Finally, the Marketing Plan has a proposed pricing document near the back of the plan that explains the "SPREAD TO HOMECARE PHARMACISTS – BASED ON DIRECT PRICES." This section goes on to show an "AWP" of "$0.74," "REIMBURSEMENT AT 80% OF AWP" of "$0.59," "DIRECT COSTS" of "$0.48," and a "SPREAD" of "$0.11 [per unit]." (DL-TX-0091056.)

160. Dey was aware that the reporting of prices such as AWP to the price databases such as First DataBank, MediSpan, and Red Book was critical to selling its drug products to pharmacies and to having those drug products reimbursed by third parties, including Medicare and Medicaid. (See description of importance of price databases to Medicaid reimbursement as pleaded by Dey, L.P. in Complaint for Injunctive Relief, Damages and Other Relief, *Dey, L.P. v. First DataBank, Inc.*, California Superior Court, Case No. 26-21019, April 15, 2003, ¶¶ 26-39.) Also, the New Product Launch Plan for Albuterol Sulfate Inhalation Solution 0.083% 3 mL included the following: "Strategy: ensure early reimbursement for Dey-Lute Albuterol through rapid notification to pharmacy reference (price) data bases. Tactic: Faxes sent to Drug Topics Red Book, First Data Bank and Price Alert, Facts & Comparisons and Medi-Span on day after approval." (Dey Laboratories, Inc., New Product Marketing Plan, Albuterol Sulfate Inhalation Solution 0.083% 3 mL, Helen Burnham, February, 1992, DEY-FLA-0026265-308).

161. Dey set the AWP and WAC for its drug products and knew well the effect that these reported and published prices had on sales to pharmacies. Dey also knew well the role that these reported and published prices (i.e., AWP and WAC) served in the third party reimbursement process, including the impact on Medicaid and Medicare reimbursement. Dey prepared a "Reimbursement Comparison Worksheet" and trained its sales representatives on its use during product launch and other sales meetings. For example, a memo to sales and account managers announcing the launch of a new product, albuterol sulfate inhalation solution 0.5%, 20 mL, states, "In this launch manual you will find a copy of the presentation you saw recently at your sales meeting, including the

launch plan, market overview, sales direction, our pricing matrix, terms, literature, a training module and copies of all announcement mailings. In addition, we included the "Multidose to Unit-dose Conversion" reprint and worksheet, and the "Retail Profit Gain" worksheet. [also known as the Reimbursement Comparison Worksheet] You used both successfully last year." (Dey Albuterol Multidose!!!!, Launch Manual, March 1996, Memo from Todd Galles to Territory Account Managers, Inside Sales Representatives, National Account Managers, Re: New Product Announcement: Dey Albuterol Sulfate Inhalation Solution 0.5%, 20 mL, dated March 4, 1996, DL-TX-0092786-813).

162. Dey set its actual selling prices to wholesalers substantially below its reported prices (i.e., AWP and WAC). In the Marketing Launch Plan for Albuterol Inhalation Aerosol, 17g (MDI) there is a price list for this new MDI version of albuterol (Dey). This price list clearly states the price per unit to each specific class of trade (set of buyers) as a percent off of AWP or other defined benchmark prices. For example, the "Wholesaler" direct price is to be "Proventil [the Schering brand] less 19%;" the price to "warehouse chains" is to be "AWP – 35%;" the price to a "Generic Distributor" is to be "15% Below Wholesalers); and the price to a "Mail Order" is to be "AWP – 36%." In other words, the actual prices to buyers in each of these classes of trade were substantially below (i.e., 19 percent to 36 percent or more) the manufacturer-reported AWP price. (MARKETING LAUNCH PLAN, Albuterol Inhalation Aerosol, 17g (MDI), DEY Laboratories, MDI PRICING, included in the document dated November 1995 and prepared by Todd Galles, DL-TX-0093357.)

163. Dey took actions to "increase reimbursement spread" for its cromolyn drug product. In a memo RE: CROMOLYN SALES UPDATE, the memo describes,

"After five months of marketing of Cromolyn, Marketing has conducted extensive analyses to determine the sales status of Cromolyn to date." In response to that analysis, program adjustments were recommended including: "Price modifications have been implemented in all retail buying groups, generic distributors, and some chain accounts. This will increase reimbursement spread. We should be more aggressive on discounting the 120's." (Memo from Robert F. Mozak, Dey, to Charles Rice, CEO, Dey, RE: CROMOLYN SALES UPDATE, dated September 28, 1994, DL-TX-0161590-607.)

164. Not only did Dey set and increase the spread amounts for its drug products, Dey also knew the impact of these spreads upon the purchase decisions of its customers. In a monthly report from Dey's CEO (Charles Rice) to his European superior, Rice reported, "Due to the less favorable spread below AWP and market pricing on Cromolyn, we are facing price reductions on this new product to stimulate movement in the last quarter." (Memo from Charles Rice, CEO, Dey, to Jean-Pierre Termier (European corporate headquarters), RE: MONTHLY REPORT – AUGUST 1994.UPDATE, dated September 28, 1994, DL-TX-0162493-495.)

165. Dey went so far as to develop a "REIMBURSEMENT COMPARISON WORKSHEET" and to link employee compensation to incentives for presenting this Reimbursement Comparison Worksheet to key customers. Several versions of the Reimbursement Comparison Worksheet were produced by Dey. (DEY-BO-0240246, DEY-BO-0239333, and DEY-BO-0239338). Dey issued a memo to its sales personnel addressing "Retail Questions." This memo begins by instructing: "Discuss and ask the pharmacist what his reimbursement is on our product. Determine if your state reimburses for saline. If not, this store is losing out and would prefer to us[e] (sic) UD [unit dose]

where they would be reimbursed for the full item." The memo goes on to explain, "It would benefit the pharmacist to get reimbursed for UD which carries a higher reimbursement amount the MD [multi dose]." Finally, the memo concludes, "Get the pharmacist to work with you to fill out the reimbursement comparison worksheet. You will need to know how your state reimburses the pharmacist. He can tell you. Some states reimburse according to AWP others use WAC pricing. You also need to know if the pharmacy is a member of any Retail Buying Groups to get his Dey price. Once all this information is obtained you can begin to fill out the worksheet to see what his profits comparison would be." ("Retail Questions" on Dey letterhead with "Reimbursement Comparison Worksheet," "Albuterol Multi Dose Worksheet," and "Albuterol Unit Dose Worksheet," DL-TX-0090869-74.)

166. The role of the incentive plan in compensation of sales personnel was described in a series of memos in 1995. (Memo from Bruce Tipton to Managed Care Team, RE: ATTACHED INCENTIVE INFORMATION, dated April 5, 1995, DEY-LABS-0282782-786.) These memos describe that: "The remaining 30% [of your incentive] (part B) is based on your goal attainment including: (1) Presentation of at least one AWP reimbursement proposal to convert multidose to Dey unit dose albuterol to a bonafide account. (2) Presentation of at least one Cromolyn conversion program to a qualified major retail chain drug customer." Later memos further specify that at least one presentation of each type per quarter is required to receive the incentive compensation.

167. Although Dey did on occasion reported an isolated AWP or WAC and related disclaimers to state Medicaid programs, these limited instances were not sufficient to inform Medi-Cal of Dey's actual transaction prices for its full product line over time.

For example, I am aware that Dey prepared, at one point in time, two letters that were circulated with an "Inter Office" memo, but it was not clear to whom and when these letters were distributed. (Internal Memo from Todd Galles (Dey) to Russ Johnston (Dey), re: New 105-01 Albuterol Multidose Medicaid letters, dated August 10, 1999, DEY077-3599-3601.) As the cover memo notes, "[t]here are two letters: one for the states requiring WAC pricing; they get the letter with both WAC and AWP prices listed, and the second letter for the other states that base reimbursement off AWP; they get the letter that lists only AWP. There are 9 states that I know of that require WAC notification. All others need only the AWP." The two letters attached serve to announce the introduction of one new drug product (Dey's albuterol sulfate inhalation solution, NDC # 49502-105-01).

168. The "WAC and AWP letter" provides the "AWP per Unit" and the "WAC per Unit" prices for this new NDC. The letter goes on to describe that, "WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers." The letter goes on to explain that because of discounts, rebates, chargebacks, administration fees and other such adjustments "WAC may well not be representative of actual market costs…" Nowhere in the letter does Dey state what the actual cost is for this new NDC. In addition, the letter does not state the relationship of the AWP or WAC, on average or otherwise, to the actual market cost. Also, the letter addresses only the one new drug product (albuterol sulfate inhalation solution, NDC # 49502-105-01).

169. The "AWP letter" provides the "AWP per Unit" for this one new drug product (NDC # 49502-105-01) and does not mention the "WAC per Unit" price for the new NDC. The letter goes on to describe that, "the Average Wholesale Price (or

"AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product." Nowhere in the letter does Dey state what the actual cost is for this new NDC. In addition, the letter does not state the relationship of the AWP, on average or otherwise, to the actual market cost. Also, the letter addresses only the one new drug product (albuterol sulfate inhalation solution, NDC # 49502-105-01).

170. Based on my experience and understanding of the Medicaid reimbursement system and state Medicaid program operations, there is nothing in this letter that would have enabled a State Medicaid agency to reimburse for the Dey product based on the "price generally and currently paid." While Dey notes in the letter that the AWP alone, or in the other letter that the AWP and WAC, are not actual market prices, Dey's letter did not provide prices that are "generally and currently paid" in the market. Also, there is no indication that Dey provided the drug price databases with the prices that are "generally and currently paid" in the market. There is nothing in this letter that would have changed the prices in the computerized commercial drug price databases known to be used by the state Medicaid drug programs including Medi-Cal. The reimbursement system is structured to use computerized price databases (i.e., First DataBank, MediSpan, or Red Book) with manufacturer-reported prices that are applied using a known formula to establish the reimbursement for an individual prescription. This system is not dependent upon, nor does it provide a means for *ad hoc* information for individual drug products to be routinely input and used as a basis for reimbursement. Even if the system could accommodate an *ad hoc* price edit for an individual NDC, there was no information in either version of Dey's letter that could have been input as the "price generally and currently being paid."

171. In light of the limited staffing and the relative lack of usefulness of the information in the Dey letter, I am not surprised that various State Medicaid pharmacy program personnel, including personnel for Medi-Cal, have testified that they did not remember the Dey letters, did not find them helpful, or filed them "in the round file." (e.g., see Deposition of Kevin Gorospe (CA), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Sep. 22, 2008, pp. 682-684; Deposition of Ayuni Hautea-Wimpee (WA), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Nov. 24, 2008, pp. 149-150; Deposition of James Parker (IL), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Nov. 18, 2008, p. 71; Deposition of Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 254-258; Deposition of Roxanne Homar (WY), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 3, 2008, p. 444; and Deposition of Suzette Bridges (AR), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 11, 2008 (Vol. 2), pp. 531-539.)

H. Mylan's Price Reporting Conduct and Impact on Medi-Cal

172. There is evidence indicating that Mylan's employees understood and monitored how the drug prices (e.g., AWP and WAC) they published through databases (e.g., First DataBank) would be used and relied upon by others. Mylan knew that its reported price information would be used in a formulaic process to set the payment to pharmacies and other providers for dispensing each specific prescription for a drug product at the NDC level to a patient in a given third party program, including state Medicaid programs. Evidence also indicates that Mylan knew that pharmacies were interested in these published drug prices for drug reimbursement purposes. [Deposition of Robert Potter, Exhibit 47, CAMylan04044071 (Letter from Stephen Krinke, Director,

Trade Relations and Government Affairs, Mylan Pharmaceuticals to Mr. Matthew Leonard, Category Manager, CVS Corporation, dated July 20, 1999.]

173. Mylan employees understood and monitored how third party payers used prices from the price databases for purposes of setting drug reimbursements to pharmacies. For example, in 1999 Mylan's Director of Trade Relations and Government Affairs (Stephen Krinke) wrote to CVS, one of the largest chain pharmacies in America, and stated "(w)e are striving to maintain AWP's (sic) on all Mylan products which will maximize your reimbursement. A significant number of Mylan AWP's (sic) have been modified in the past two months. Below is a list of products you are currently purchasing from Mylan which have had AWP increases… We will continue to monitor our AWP's (sic) and make appropriate adjustments." [Deposition of Robert Potter; Letter from Stephen Krinke, Director, Trade Relations and Government Affairs, Mylan Pharmaceuticals to Mr. Matthew Leonard, Category Manager, CVS Corporation, dated July 20, 1999 (Exhibit 47, CAMylan04044071)]. In this letter alone, 35 different drug names were identified by Mylan as experiencing AWP increases in the past two months. This communication provides evidence that Mylan knew that its published prices (e.g., AWP and WAC) were important to pharmacies and that these prices could be controlled to "maximize reimbursements" paid to pharmacies at the expense of payers such as Medicaid. [Deposition of Anthony Mauro, Mylan, June 5, 2001, Exhibit 11, e-mail re: Medicaid State Reimbursement; see also, Exhibit 19, New Product Pricing, Terazosin, TX MYLAN 00201945-968; Exhibit 20, New Product Plan Summary, Nifedipine ER, Novermber 5, 1999; CA MYLAN 02748871-872; Exhibit 21, Hydrochlorothiazide, November 5, 1999, and Exhibit 22, Carbidopa and Levidopa, December 7, 1999 CA

MYLAN 02748867-868; and see also, Exhibit 8, Nifedicpine ER, Mylan National Account Managers Meeting, May 4-5, 2000, FAQs, TX MYLAN 00399800-802.]

174. An internal memo at Mylan advises National Account Managers and other sales personnel that "We will continue to monitor all Mylan products and make adjustments to ensure competitive/maximal AWP's (sic). Please use these increases as a selling tool with your accounts." [Memo from Steve Krinke, Director of Trade Relations and Government Affairs, Mylan Pharmaceuticals to Tom Darby . . . National Account Managers, Subject: Additional AWP Revisions dated July 8, 1999 (Krinke Exhibit 13, MAMylan006253).] This memo shows that Mylan increased AWPs and that these "increases" were used as a "selling tool."

175. Mylan also was interested in training its personnel on reimbursement matters. The individual who reported prices to state Medicaid programs, Steve Krinke (Director of Trade Relations and Government Affairs), was requested to "put together a tutorial on market pricing" that was to include "specific points" on "MAC HCFA / State and private 3rd party MACs, when calculated and how; Generic vs. brand reimbursement models on typical 3rd party programs; Copy of state medicaid reimbursement models; and Copies of any customer reimbursement articles." [Memo from Robert Cunard to Steve Krinke, Director, Trade Relations and Government Affairs, Mylan Pharmaceuticals, Subject: Reimbursement Outline dated January 8, 2001 (Potter, Exhibit 40, CAMylan020042862)]. A powerpoint presentation describing Mylan's Sales and Marketing Department and its functions reveals an awareness that drug reimbursement was dependent upon state Medicaid formulary placement and the publication of manufacturers' prices through pricing compendia such as First DataBank. [See Potter

Exhibit 14, "Contracts & Pricing, A Customer Service Overview," TXMylan03925536-52; see also, Deposition of Joseph Duda, October 14, 2008, Exhibit 5, TXMYLAN 03925536-552; Deposition of Joseph Duda, Exhibit 8, Sales and Marketing Department Overview, TXMYLAN 00428360-72.] This presentation also indicates that Mylan recognized "keys to influence sales" included the "spread of AWP."

176. Mylan also created a "Reimbursement Comparison Worksheet" which calculated reimbursement spreads on Mylan drugs compared with the spreads on competing brand drugs and other generic drugs for Medicaid and private pay plans. [Potter, Exhibit 11, Medicaid Reimbursement Comparison Summary, MYLCA 000123; see also, Potter, Exhibit 12, Medicaid Reimbursement Comparison Worksheet, MYLCA 000111-113; see also, Memo from Robert Cunard, Mylan Pharmaceuticals to Mr. Moldin, Subject: Drug 7 Information, Attachment, Private Pay Reimbursement Comparison Worksheet (Potter Exhibit 10, MYL000956).] Other versions of this reimbursement comparison document in the same, or a similar, format appear in other Mylan business records as this price spread comparison template was utilized for multiple drugs on multiple occasions. [See Memo from Jason Harper to Drew Blowers, et. al., Subject: Nifedipine ER Reimbursement Comparison dated March 14, 2000 (Potter Exhibit 9, TXMylan02719468).]

177. Documents, such as those referenced above, indicate that Mylan was aware of its pharmacy customers' interest in drug pricing and reimbursement information. Particularly, the customers were interested in the reimbursement amounts from payers such as Medicaid and in the calculated payment amounts using Mylan's published prices such as AWP and WAC.

I. Sandoz' Price Reporting Conduct and Impact on Medi-Cal

178. There is evidence indicating that Sandoz' employees understood and monitored how the drug prices (e.g., AWP and WAC) they published through databases (e.g., First DataBank) would be used and relied upon by others. Sandoz knew that its reported price information would be used in a formulaic process to set the payment to pharmacies and other providers for dispensing each specific prescription for a drug product at the NDC level to a patient in a given third party program, including state Medicaid programs. Evidence also indicates Sandoz knew that pharmacies were interested in these published drug prices for drug reimbursement purposes. [CVS Proposal (prior to June 1, 2001), Deposition of Hector Armando Kellum, Exhibit 16, SANDOZ WISC 0064552-55; and Deposition of Ira Baeringer, October 15, 2008, p. 80, lines 4-20; SANDOZ WISC 0546364 (Sample Pricing Model for Brands and Generics, Kevin Galownia, Senior Pricing Manager, Sandoz).]

179. As a general matter, responsible personnel at Sandoz admit Medicaid reimbursement eligibility (i.e., coverage) was important to a pharmacy's decision to stock a given generic product. [See Deposition of Ronald Hartmann, Manager of Government Affairs, Sandoz, April 23, 2008 at 106:5 to 108:10.]

180. Sandoz sales personnel also understood pharmacies would be less likely to purchase drugs which were not covered by Medicaid. [Deposition of Warren Pefley (Sales, Sandoz), October 8, 2008, at 329:17 to 330:4.] In addition, sales persons fielded questions from customers about reimbursement and provided AWPs to customers who performed reimbursement spread evaluations. [See Lubke, Director of National Accounts, Sandoz, October 20, 2008 at 63:13 to 64:13; 129:23 to 133:20.] Sandoz

witnesses also understood increases in published AWP and WAC prices would result in increased reimbursements and increased pharmacy profits. [See, for example, Deposition of Hector Armando Kellum, Manager of National Accounts (formerly Credit Manager and Finance Manager), Geneva (Sandoz), October 10, 2008 at 222:16 to 226:23.] Documentation produced by Sandoz indicates Sandoz modeled, and/or calculated, the reimbursement increase which would result from AWP and WAC manipulations. [See Deposition of Hector Armando Kellum, Manager of National Accounts (formerly Credit Manager and Finance Manager), Geneva (Sandoz), Exhibit 12.]

181. In addition to understanding customers' interests in published pricing for reimbursement purposes, Sandoz also transmitted information that described increasing reimbursement spread amounts to customers such as chain pharmacies. [Deposition of Hector Armando Kellum, Manager of National Accounts (formerly Credit Manager and Finance Manager), Geneva (Sandoz), October 10, 2008, 234:11 to 240:7; and Kellum, Exhibit 13.]

182. Documents, such as those referenced above, indicate that Sandoz was aware of its pharmacy customers' interest in drug pricing and reimbursement information. Particularly, the customers were interested in the reimbursement amounts from payers such as Medicaid and in the calculated payment amounts using Sandoz' published prices such as AWP and WAC.

J. Impact of Dey, Mylan and Sandoz Conduct on Medi-Cal

183. Pharmaceutical manufacturers are generally well aware of the reimbursement policies and systems of major payers, specifically including Medicaid and Medi-Cal. Evidence in this case showing that Dey, Mylan, and Sandoz were aware of

Medicaid and Medi-Cal reimbursement policies is totally consistent with my general understanding of the industry over the last 30 years. For example, pharmaceutical manufacturers know that they must report prices to the pricing compendia in order to have their drug products be saleable in the marketplace due to reimbursement practices. Pharmaceutical manufacturers know that the prices they report to the pricing compendia will be used by third party payers, including government third party payers, to set the amount at which the health care providers will be reimbursed for drugs that are dispensed.

184. Dey, Mylan, and Sandoz have reported inflated prices to the commercial price databases used by Medi-Cal that were not reasonably or fairly indicative of the "prices generally and currently paid by providers" in the marketplace, during the period covered by the Complaint. These inflated price reports have caused the state Medicaid drug programs, and Medi-Cal, to pay inflated reimbursement amounts for the drug products specified in the Complaint.

185. The difference between Dey's, Mylan's, and Sandoz' inflated price representations to the commercial drug price databases and the actual net cost to pharmacies and providers created a substantial "spread." Consequently, the Medi-Cal drug program substantially overestimated the acquisition cost of the drugs to providers and, as a result, paid more than they intended, or an unknown amount in excess of the amount they intended, to pay these providers.

186. Based on the extensive sales of drug products through contracts with provider-customers, pharmaceutical companies, including Dey, Mylan, and Sandoz are intimately familiar with the prices that the customers pay for the company's drug

products. Even if the sale to the customer is delivered through a wholesaler, the contract price has typically been negotiated in advance between the manufacturer and the customer, thus the actual contract price is fully known to the manufacturer. In the cases of Dey, Mylan and Sandoz, the Defendants would also have been aware of the actual net prices in situations where the company utilized a direct sales model, that is, contracts that resulted in direct sales to a provider.

187. Dey, Mylan, and Sandoz had information readily available, at the time that they reported inflated price information to the commercial price databases, which would have enabled them to report price information which fairly and reasonably represented the prices generally and currently paid in the marketplace, had they chosen to use this information. The information available to Dey, Mylan, and Sandoz was the exact type of information that they used when making pricing and other business decisions in the ordinary course of their business. [Dey, L.P., Average Price – Shelf Carton, December 2000, DL-TX-0078119-121; Dey, L.P., Average Price – eaches, December 2000, DL-TX-0078122-124; Dey Laboratories, Bid Reports: July/August, 1995 and Year-to-Date, DL-TX-0079904-913; Deposition of Joseph Duda, Exhibit 8, Sales and Marketing Department Overview, TXMYLAN 00428360-72; Deposition Joseph Duda, October 14, 2008, Exhibit 3, April 28, 2003, Rite [Aid] Contract On Contract vs. Not On Contract, TXMYLAN 00315908-925; Deposition of Kristy Ronco, Sandoz, April 10, 2008, p. 26-27.]

188. I am aware that Dey, Mylan, and Sandoz have responded to California's complaint in their answers, in part, by stating that any and all actions taken were taken in good faith and in accordance with established industry practice. (Dey Answer,

Affirmative Defense 7, 11, and 18; Mylan Answer, Affirmative Defense 7, 11, and 18; and Sandoz Answer, Affirmative Defense 8, and 11). Even if true, this price reporting behavior was contrary to the public interest as historically reflected in Medicaid and Medi-Cal program policy, principles, statutes, and regulations and routinely reported in various other places including the NPC Medicaid Book, well-known to Dey, Mylan, and Sandoz on an annual basis from well before 1990 to the present.

189. State Medicaid programs are usually sparsely staffed, with the employee(s) having responsibility for a wide range of issues, initiatives and systems such as pricing and reimbursement, drug utilization review, drug rebates, state preferred drug list development and maintenance, and other issues. This limited staff for the Medi-Cal program does not have the time to review all drug product prices on a routine basis in addition to their other job responsibilities. State Medicaid drug programs pay for somewhere between 20,000 and 60,000 different drug products (NDCs). California regulations require that "the EAC, the FAC, and the MAIC/MAPC shall be updated by the Director . . . no less often than every 30 days for drug products." [Cal. Code Regs. tit. 22 §51513(a)(11), effective 3-1-95]. It simply is not feasible to monitor and manually update all of these drug (NDC) prices on a monthly basis.

190. The Medi-Cal program has contracted with Electronic Data Systems (EDS), a private firm, to perform claims processing and payment services and other drug benefit operations for the Medi-Cal prescription drug program throughout the relevant period in this case, 1994 through 2004. States like California, and the claims processors acting on the state's behalf, did not use WAC in their reimbursement process. Given the relatively limited staffing of State Medicaid programs, it was not common for, and not

practically possible for, Medi-Cal employees to "eyeball" or review the AWP and WAC drug pricing data on a routine basis for all 20,000 to 60,000 drug products (NDCs) paid for, or potentially paid for, by the Medi-Cal drug program.

191. Manufacturers developing innovator brand name drugs and pharmaceuticals are traditionally protected by patents and permitted to set prices in the United States which are typically higher than the prices the same manufacturer charges for the same innovator drug abroad. Once the patent or other market exclusivity protection expires, however, the drug can become subject to generic competition that creates market conditions that cause the price of the drug, or its generic equivalents, to fall. As a result, consumers and others paying for the drug, including state Medicaid drug programs as well as Medicare, should benefit from healthy price competition that should lead to lower prices. The deceptive conduct by Dey, Mylan, and Sandoz, as alleged by the plaintiffs, prevents the lower prices resulting from healthy market conditions from being captured by payers such as state Medicaid drug programs including California's Medi-Cal program.

192. In summary, Dey, Mylan, and Sandoz clearly understood the role of drug price databases and the role of reported and published prices (i.e., AWP, WAC, and/or DP) in the payment for prescriptions by third party programs, including Medi-Cal and Medicaid. Dey, Mylan, and Sandoz actively monitored and reported to the drug price compendia (i.e., Blue Book, MediSpan, and Red Book) the AWP that was published for their respective drug products.

VII. IMPORTANCE OF MEDICAID AND MEDI-CAL TO PHARMACEUTICAL MANUFACTURERS AND OTHER TOPICS

193. The Medicaid program is very important to pharmaceutical manufacturers. Medicaid prescription expenditures have accounted for 8% to 15% of total U.S. outpatient prescription dollars over the past 15 years (i.e., 1991 to 2005) and Medicaid paid for 8% to 14% of the total number of outpatient prescriptions dispensed in the United States over the past 15 years (i.e., 1991 to 2005). During the period from 1996 to 2004, the prescriptions paid for by Medi-Cal represented 10.3% to 15.8% of all prescriptions in California. [National Association of Chain Drug Stores (NACDS), *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006].

194. As noted earlier in this report, up until January of 2006, the Medicaid drug program was the single largest outpatient drug program in the United States.

195. Medicaid is also important to pharmaceutical manufacturers because their pricing behavior in the broader pharmaceutical market may affect the rebates that must be paid under the voluntary agreement with the Secretary of the Department of Health and Human Services to enable participation in the national Medicaid Drug Rebate Program.

196. The Medicaid program and the operational details of drug coverage and reimbursement on a state-by-state basis, as well as Medicare reimbursement for drugs under Part B, are essential information for key personnel at every pharmaceutical manufacturer. This coverage and reimbursement information is important for persons working in business strategy, pricing, product management, marketing, and other units.

197. Medicaid is so important that pharmaceutical manufacturers support the compilation of detailed Medicaid drug program information and experience on an annual basis. Drug companies also engage in lobbying activities related to federal and state legislative and regulatory actions that may influence access to their drug products and the amounts providers are reimbursed for these drug products by Medicaid, Medicare, or other government programs.

A. The National Pharmaceutical Council and the NPC Medicaid Book

198. The National Pharmaceutical Council (NPC) is a group of pharmaceutical companies "engaged in the discovery, development, production, and marketing of innovative prescription medicines." The National Pharmaceutical Council, Inc. was founded in 1953 and in 1992 had twenty-nine member companies. The 2005/2006 version of the NPC Medicaid Book lists twenty member companies on its back page. The membership includes some new firms, but the number of members has declined over time due, in part, to many mergers and acquisitions among drug firms.

199. Sandoz was aware of, and had access to, this publication since Sandoz (or its parent firm Novartis Pharmaceuticals Corporation) has been a sponsoring member of the National Pharmaceutical Council since 1983 or before. [30] [NPC, *Pharmaceutical Benefits*, annual volumes, 1983 to 2006, membership list on back cover]. Dey was also aware of, and has referenced, the National Pharmaceutical Council publications on Medicaid program reimbursement in internal documents and communications as far back as 1995. (Memo from Dey Laboratories to Beth Raider, Price Alert and Pharmacy Blue

[30] The back cover of the NPC's annual volume of *Pharmaceutical Benefits Under State Medical Assistance Programs* lists the member companies and, prior to 1983, the NPC letterhead listed the member companies.

Book Update, May 30, 1995, attachment "Medicaid Rx Reimbursement Report, Drug Topics, February 6, 1995, Source: National Pharmaceutical Council.)

200. The Medicaid drug program is so important that the NPC publishes an annual volume titled "Pharmaceutical Benefits Under State Medical Assistance Programs" (known as the NPC Medicaid Book). A "Dear Reader" letter in the preface to the 1992 edition of this publication says, "Since 1965, it has been published by the National Pharmaceutical Council to support your evaluation of Medicaid program characteristics." [NPC Medicaid Book, 1992]. The NPC Medicaid Book was first published in 1965 and continues to be published every year. The 2005/2006 edition marked the 40th annual volume of the NPC Medicaid Book.

201. The NPC Medicaid Book is compiled from data obtained from the Health Care Financing Administration (now the CMS), from a survey of "state Medicaid program administrators and consultants," and from other federal agencies and organizations. [National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1992, p.iii]. The NPC Medicaid Book preface in the form of a "Dear Reader" letter explains that NPC "provides services to pharmacists, manufacturers, professional associations, colleges of pharmacy, physicians, medical schools, government offices, and consumers concerning key aspects of health care."

202. As noted in the *Introduction*, the NPC Medicaid Book "has become a standard reference and invaluable resource in government offices, research libraries, consultancies, the pharmaceutical industry, numerous businesses, and policy organizations." [NPC Medicaid Book, 2005/2006, p. 1-3].

203. The NPC Medicaid Book is updated every year and profiles each state's Medicaid program and related policies. The NPC Medicaid Book also contains information on all states, as well as the District of Columbia.

204. The NPC Medicaid Book makes clear the extent to which Medicaid relies upon published prices. This book also contains the following types of information: (1) an overview of the Medicaid program, its history, and related regulations; (2) socio-demographic statistics, by age, race, insurance, income, and employment, for the fifty states and the District of Columbia; (3) Medicaid pharmacy program characteristics, drawn largely from the annual survey of state pharmacy program administrators and Medicaid pharmacy program characteristics, such as total expenditures, drug payments, drug benefit design, and pharmacy payment and patient cost sharing; (4) detailed profiles of the states' Medicaid pharmacy programs and a description of medical assistance benefits and eligibles, drug payments and recipients, benefit design, pharmacy payment and patient cost sharing, use of managed care, and state contacts; (5) profiles of State pharmaceutical assistance programs, for those states with such programs; (6) a list of state contacts, CMS regional offices and Medicaid program personnel; (7) a national level summary on total Medicaid program recipients by type of service; (8) data on total number of drug recipients for each state and the nation; (9) provisions of the current Medicaid drug rebate law; (10) the list of CMS federal upper limits on multiple source products; and (11) a glossary and list of acronyms.

205. The size and importance of the Medicaid program is so great that any key person in an area such as marketing, pricing and reimbursement, product management, or business strategy at a pharmaceutical company would have to be aware of the payment

policies of Medicaid, or at least of where to find information on such policies. Key personnel at major pharmaceutical companies, including Dey, Mylan and Sandoz, would have been aware of the NPC Medicaid Book and most probably had a copy of the book in their offices.

B. Price Disclosures of Relator

206. Until the efforts and disclosures of Ven-A-Care, I am not aware of any government or other published study or report that documented the inflation and manipulation of prices reported by certain drug manufacturers. Ven-A-Care's disclosures of reported price manipulation and inflation by drug manufacturers, such as Dey and Sandoz, were initially provided in August of 1995 and led to government investigations and litigation.

207. I am familiar with Ven-A-Care's 1998 presentation to Medi-Cal and the California Office of the Attorney General. Also, I am familiar with the 2000-2001 investigation led by Congressman Pete Stark and the House Committees on Energy and Commerce and Ways and Means, including the information provided by Ven-A-Care pursuant to the Commerce Committee's subpoena. As an expert in pharmaceutical economics for more than 30 years, it is my opinion that the information provided by Ven-A-Care to these entities and other governmental bodies was significant in illuminating certain drug manufacturer pricing and marketing activities. This type of information was not typically made available, or provided by, pharmaceutical manufacturers to anyone in the marketplace. The Ven-A-Care revelations eventually enabled the government to understand the role of conduct by certain drug manufacturers and how such activities led to a detrimental impact on Medi-Cal reimbursement rates and program expenditures.

208. A sampling of government studies conducted subsequent to the disclosures of Ven-A-Care is listed below:

a. Brown, June Gibbs. Review of Pharmacy Acquisition Costs Reimbursed Under the Medicaid Prescription Program of the California Department of Health Services. Department of Health and Human Services, Office of Inspector General, May 31, 1996. A-06-95-00062;

b. Brown, June Gibbs. Appropriateness of Medicare Prescription Drug Allowances. Department of Health and Human Services, Office of Inspector General, May 1996.OEI-03-95-00420;

c. Brown, June Gibbs. Suppliers' Acquisition Costs for Albuterol Sulfate. Department of Health and Human Services, Office of Inspector General, June 1996.OEI-03-94-00393;

d. Brown, June Gibbs. Excessive Medicare Payments for Prescription Drugs. Department of Health and Human Services, Office of Inspector General, December 1997.OEI-03-97-00290;

e. Brown, June Gibbs. Need to Establish Connection between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs. Department of Health and Human Services, Office of Inspector General, May 1998, OEI-03-97-00052;

f. Brown, June Gibbs. The Impact of High-Priced Generic Drugs on Medicare and Medicaid. Department of Health and Human Services, Office of Inspector General, July 1998.OEI-03-97-00510;

g. Medicare Reimbursement of Prescription Drugs. Department of Health and Human Services, Office of Inspector General, January 2001.OEI-03-00-00310;

h. Rehnquist, Janet. Medicaid's Use of Revised Average Wholesale Prices. Department of Health and Human Services, Office of Inspector General, September 2001. OEI-03-01-00010;

i. Rehnquist, Janet. Medicaid Pharmacy-Actual Acquisition Cost of Brand Name Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, August 2001. A-06-00-00023;

j. Rehnquist, Janet. Medicaid Pharmacy- Actual Acquisition Cost of Generic Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, March 2002. A-06-01-00053;

k. Rehnquist, Janet. Medicaid Pharmacy- Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, September 2002. A-06-02-00041; and

l. Myers & Stauffer LC. Prepared for the Texas Health and Human Services Commission. Determination of the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program. August 2002.

D. Government GAO and OIG Studies

209. Academic and government researchers have not had ongoing or reliable access to pharmaceutical manufacturers' actual prices, or detailed information about marketing tactics, such as those disclosed by Ven-A-Care. This type of information would be essential to a determination of whether an individual drug company has reported prices that varied from those prices which would be consistent with the expected relationship of AWP to WAC. OIG and GAO reports have suggested that there is consistent relationship between AWP and WAC. That is, the WAC for brand name drugs, representing the majority of dollars expended for Medicaid reimbursed prescriptions, have historically been within 20% or less of AWP.

210. The federal and state governments, including the U.S. Congress, have repeatedly attempted to study the relationship between drug prices published by price publishing services and the range of prices generally and currently paid by prudent purchasers in the marketplace. These OIG and GAO reports showing differences between the prices published in the drug price databases (AWP, WAC, and DP) and actual audited invoice prices by design covered a limited time frame, focused on a limited set of drugs and a limited set of providers in the sample, and presented simple and weighted averages or high to low price ranges that are not generalizable to all drug products at all points in time for all purchasers. The limited data from these government studies was not sufficient to routinely determine that there were substantial differences between the published benchmark prices (i.e., AWP, DP, and WAC) and the actual

invoice prices to specific pharmacies and other providers for specific drug products from specific manufacturers over time.

211. These GAO and OIG studies were designed to provide a one-time snap shot look at very focused and certain pricing issues for a limited set of drugs that were already known, or suspected. These studies were not designed to look for new, or unknown, pricing issues or marketing practices in general. Additionally, many of these GAO and OIG studies focused on pricing issues related to the formulaic spread (i.e., AWP to WAC, or invoice price) and not the hidden spread from WAC (or invoice price) to actual acquisition cost.

212. The methodology and results of these GAO and OIG studies were subject to criticism by academic experts and various retail pharmacy providers who purchase both brand and generic drug products and provide them to Medicaid recipients. [Michael Johnsrud, Marv Shepherd, Kenneth Lawson, A Review of the Office of Inspector General Report: Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products, The Center for Pharmacoeconomic Studies, University of Texas at Austin, December 2001, 5 pp.]. The University of Texas critique of the 2001 OIG study enumerated multiple concerns with the method and results of the OIG study including: (1) non-representative sample strata; (2) no correction for non-respondents; (3) non-representative pharmacy invoice samples; (4) inappropriate extrapolation from limited sample to nationwide estimate; (5) inconsistent categorization of brand vs. generic products; (6) discounts not weighted by Medicaid sales; (7) not all drugs are paid for at the AWP rate; and (8) misleading presentation of estimation variance. The University of Texas critique concludes that there were “significant issues relating to methodology and

extrapolation of national estimates based on what appears to be an unrepresentative sample of pharmacies and invoices." Two major pharmacy organizations reiterated these criticisms of the OIG study. Both the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) issued press releases questioning the findings of the OIG report. [NACDS & NCPA, University of Texas Study Questions Findings of OIG Brand Name Drug Analysis, December 6, 2001.]

213. Even after these GAO and OIG studies, there continued to be an absence of accurate actual price information either directly from drug manufacturers or indirectly through the drug price compendia. This continued absence of accurate actual price information prevented the state Medicaid programs and other payers from being able to develop reimbursement systems that paid providers a price that was as close as is feasible to the price generally and currently paid by providers. Conversely, the prescription reimbursement systems that paid providers under state Medicaid programs and other third party programs would have worked as intended for the purpose of providing a reasonable estimate of acquisition costs if drug manufacturers had made public and reported prices generally and currently paid by those providers.

214. An additional limitation to these studies was the lack of transaction price information from drug manufacturers and other participants in the market. The GAO and OIG did not usually have the full cooperation of drug manufacturers or providers in obtaining access to transaction level pricing data. In the limited instances where transaction price data has been available to the government or academic researchers, this data has been restricted in use and labeled as 'proprietary and confidential' by drug manufacturers.

215. These government studies were not designed to identify the reasons for the larger variances that were noted in the reports. Also, the government studies did not differentiate between variances that resulted from the activities of specific drug manufacturers rather than the existence of a large range of prices paid by prudent purchasers.

216. No one study or set of isolated studies focused only on comparison of drug product prices would be sufficient to select, establish, or operate an entirely new system for setting reimbursement rates for prescriptions under the Medicaid or Medi-Cal drug program on a comprehensive and ongoing basis across time. Simply knowing an "average" difference between published AWPs and invoice prices for a certain set of drug products at one point in time would not be sufficient to implement an ongoing reimbursement system that used an across the board discount off of AWP to pay pharmacies for providing prescriptions to Medicaid recipients.

217. In summary, the government studies including those conducted by GAO and OIG had multiple shortcomings. First, these government studies, in general, lacked specificity—that is, they did not usually identify specific drug manufacturers or specific drug products and the related prices paid versus the prices reported. Second, these government studies were unreliable for numerous reasons as identified by the University of Texas Center for Pharmacoeconomic Studies and by others. Third, while these government studies have suggested that there are issues with respect to estimating acquisition cost, the studies did not provide sufficient information to use for changing the reimbursement system for prescription drugs under Medicaid across all drug product types and over time. Finally, even after all of these government studies, drug

manufacturers continue to report prices to the commercial drug price compendia that are substantially inflated when compared to prices generally and currently paid by those providers.

VIII. SUMMARY

218. The Medicaid drug reimbursement system is based upon the consistently stated intention of reimbursing for drug products at their actual price, that is a price "as close as feasible to the price generally and currently paid by the provider" – a concept referred to in Medicaid program regulations and policies as 'estimated acquisition cost.' Medi-Cal statutory language says ""estimated acquisition cost" means the Department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." [California W&I Code § 14105.45 (effective date August 16, 2004).] This language is substantially similar to the California statutory and regulatory language throughout the period at issue in this case.

219. Third party drug reimbursement systems, including Medicaid and Medi-Cal, depend upon current and accurate price information reported directly by drug manufacturers to the commercial drug price database publishers. The payment systems of Medicaid and Medi-Cal have relied upon prices reported by drug manufacturers, including Dey, Mylan, and Sandoz to the commercial drug price databases as the basis for determining the estimated acquisition cost and for setting specific reimbursement amounts for individual prescriptions.

220. Actual transaction prices are not readily available for private or public third party payers (including Medicaid and Medi-Cal) to use as a basis for setting specific reimbursement amounts for individual prescriptions. The actual prices of drug manufacturers are considered by the manufacturers to be proprietary and confidential and are not made public.

221. The AMP was created to implement the Medicaid drug rebate program, but it was not created to serve as a payment and reimbursement system. The statute and regulations related to AMP prohibit the use of AMP for any purpose other than implementation of the drug rebate program.

222. There is no readily available substitute for the commercially published prices (i.e., AWP, DP, and WAC) widely used for payment and reimbursement systems by third party programs.

223. Dey, Mylan and Sandoz reported prices to the commercial drug price databases that were inflated in relation to actual drug prices. When Dey, Mylan and Sandoz reported inflated prices to the commercial drug price databases, those inflated prices resulted in the Medicaid and Medi-Cal programs paying more than they otherwise would have paid for a given prescription. These payments resulted in Medicaid and Medi-Cal spending more of the federal and state government resources than they otherwise would have spent for these drug products.

Dated: June 30, 2009

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